UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: CELGENE CORPORATION, INC. SECURITIES LITIGATION.

CIVIL ACTION NUMBER:

2:18-cv-4772-JMV

Oral Argument

Frank R. Lautenberg Post Office and Courthouse
Two Federal Square
Newark, New Jersey 07102
September 7, 2023

B E F O R E: **THE HONORABLE JOHN MICHAEL VAZQUEZ, UNITED STATES DISTRICT COURT JUDGE**

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(PROCEEDINGS held via Zoom videoconference, before the HONORABLE JOHN MICHAEL VAZQUEZ, United States District Court Judge, on September 7, 2023.)

THE COURT: Good morning. We're on the record in the matter of *In Re: Celgene Corporation Securities Litigation*. The civil number in this case is 18-4772.

Can I please have appearances, starting with plaintiff.

MR. CECCHI: Good morning, Your Honor. James Cecchi, Carella Byrne, on behalf of plaintiffs and the putative class.

With me today are Rocky Kravetz, Adam Wierzbowski, and Sal Graziano from Bernstein Litowitz; also, Matt Mustokoff, Andy Zivitz, and Sean Handler from Kessler Topaz.

THE COURT: Good morning.

For the defense.

MR. LUSTBERG: Good morning, Judge. Lawrence S. Lustberg and Kate Janukowicz from Gibbons who are counsel for the defendants. With us are our friends and colleagues from Jones Day. Nina Yadava in particular will be providing oral argument today, and I'll let her introduce our colleagues from Jones Day.

MS. YADAVA: Good morning, Your Honor. Nina Yadava from Jones Day on behalf of the defendants. I'm joined by my colleagues here Robert Micheletto, Rajeev Muttreja, and Sarah Efronson, all from Jones Day.

THE COURT: Okay. Good morning, counsel.

By way of background, we're having oral argument on defendants' motion -- Celgene's motion for summary judgment. While the parties are aware of the standard, for purposes of the record, I want to note that a moving party is entitled to summary judgment where the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.

Fact is material when it might affect the outcome of the suit under the governing law and is genuine if the evidence is such that a reasonable jury could return a verdict for the non-moving party.

In reviewing a motion for summary judgment, I'm not permitted to make any credibility decisions and I have to look at the evidence in the light most favorable to the non-moving party and give the non-moving party the benefit of all justifiable and reasonable inferences. As the parties know, in short, this is a sufficiency determination, not one of weighing.

As to the elements under section 10(b) and Rule 10b-5, the parties are in agreement, but because that's what the materiality standard will be judged against, I want to make clear that, first, defendant must make a misstatement or omission of a material fact. Whether it's false or misleading is measured by that of a reasonable investor.

With scienter, in connection with the purchase or sale

of a security upon which the plaintiff reasonably relied and that the reliance was proximate cause of plaintiffs' injury.

We're dealing with two different drugs at this point: the Otezla drug -- and, counsel, can you just tell me -- I want to make sure I pronounce the second drug correctly. I've read it a thousand times. I've never had to say it.

Is it "ozanimod"?

MS. YADAVA: "Ozanimod," Your Honor.

THE COURT: "Ozanimod." Okay. There are several statements, primarily with Ms. Curran, as to the Otezla drug and primarily Mr. Smith as to ozanimod.

I'm going to permit counsel to give me an introduction to their arguments. I want to give the parties the benefit of my preliminary review. Again, it's only a preliminary review.

As to Otezla, there certainly seems to be genuine disputes of material fact that would preclude summary judgment at this stage.

As to ozanimod, I think the defendants have done a good job showing that at least they should be entitled to summary judgment as to Smith's April and July statements of 2017. The November statements are not as clear to me.

The reason for that, so plaintiffs are prepared, is because when I did go back and review the information, it does appear that during the critical time frame, particularly going into April, Celgene had not yet identified that it was a

metabolite. There was concerns that it might be and what that might ensue if it is a metabolite.

Similarly, right before Smith's statement, all I have in front of me at this point is the e-mail that he received from Martin which did not seem to give any indication that there was going to be a problem.

Again, that's just my preliminary view. I can be swayed, but I figure it will help the parties direct their arguments.

I'll hear first from the defendant because it's their motion.

MS. YADAVA: Your Honor, thank you.

I'd like to take five to six minutes just to present my opening arguments, and I'd like to save most of my time for rebuttal to respond to plaintiff and their slides.

THE COURT: Absolutely.

MS. YADAVA: So I'll start with a brief opening.

Your Honor, AMF has targeted a handful of innocuous statements made by Celgene and its former officers about two different drugs, as you mentioned, and they have tried to ascribe a fraudulent intent; but after years of discovery, AMF has failed to find any evidence to support their theories, and their claims on both drugs must be dismissed for multiple reasons: falsity, scienter, and loss causation.

The information they provided in their slides is

nothing new. It is all entirely information that we have addressed in our reply brief and explained why it's irrelevant.

But beginning with the two remaining statements on Otezla, I understand that Your Honor is inclined to find that there may be questions of material fact here, but the truth is, when we look at all of the spaghetti that the plaintiffs have thrown up at the ceiling, none of it actually impacts the legal analysis.

AMF has failed to show a triable question of fact on April because when it comes to the initial inquiry to falsity, AMF has no evidence that Curran's statement of opinion that she believed net sales would rebound and why -- and remember, Your Honor, this is an opinion statement -- there's no evidence that it was false under any of the three prongs of the *Omnicare* standard.

All of the evidence shows that, one, she believed her statement; two, she did not embed any false facts; and, three, she did not omit material facts about her inquiry or about her knowledge that actually conflict with what she said.

Even if Your Honor were to find that the statements were false, which Your Honor shouldn't, with regard --

THE COURT: By the way, I'm not making a finding that they're false.

MS. YADAVA: I understand.

THE COURT: I'm not the jury. I'm just determining whether there's a genuine dispute of material fact.

MS. YADAVA: Apologies, Your Honor.

Even if you were to find that there was a genuine dispute about material fact about falsity, plaintiffs have no evidence that Curran intended to defraud or that she meets the high bar for recklessness in this circuit.

Indeed the record shows that just a few days before her statement she sought guidance and asked her colleagues whether they believed net sales would rebound and why. She simply repeated part of that information and she characterized data in charts, Your Honor, that she presented at the same time as her statements.

Third, on loss causation, AMF wants the Court to believe that all bad news about sales of a drug are corrective of everything positive that has ever been said about sales of that drug, but the standard for loss causation, Your Honor, is far more exacting than that.

And what Curran said in April are apples to the October guidance reduction's oranges. AMF fares no better on Curran's July statement for largely the same reason.

I'll start with loss causation because that's where we just ended on April. But Curran's July statement addresses three things: it addresses second quarter performance, market share, and prescriber adoption and says not a word about sales

guidance.

While the alleged corrective disclosure addresses sales guidance with a commentary on market growth and discount strategies, this is not loss causation. In any event, AMF cannot show falsity because it has no evidence that Curran's July statement was false or misleading, given the only parts of it that were not vague expressions of optimism were accompanied by the underlying data that it sought to characterize.

Just as this Court initially held with AMF's claims regarding GED 301 that were dismissed at the outset of this case, even if unduly optimistic statements -- pardon me, even unduly optimistic statements are not actionable when the underlying data itself is publicly available, and this is exactly what we have in July.

AMF again cannot show scienter because even if investors understood something different than what Curran intended, which AMF has no evidence of, there's no evidence in the record that Curran intended to mislead or that her conduct constituted an extreme departure from the standards of ordinary care.

Falsity and scienter, Your Honor, are entirely distinct prongs. Your Honor could find in our favor on either of those, finding there's no triable question of material fact on either falsity or scienter or loss causation, so all three of

these independent grounds lead to finding in favor of defendants.

AMF fares no better -- as Your Honor has initially thought, fares no better when it comes to defendants' innocuous statements about filing the ozanimod NDA or the data therein because they fail on both scienter and loss causation.

Your Honor, we said this in our brief and I'll say it again, but AMF offers a theory that makes absolutely no sense. They suggest that everyone at Celgene was rushing to get this product to market but at the same time they filed an NDA they knew would be rejected.

Of course their rejected NDA would cause delay, not expedition. In any event, AMF throws up, as it does in Otezla, a bunch of irrelevant facts which only with hindsight try to cast doubt on the NDA itself; but this case is not about whether it was a good idea to file the NDA. It is about whether Smith and Martin intentionally or recklessly misled the market by stating that Celgene would file the NDA by the end of the year, which it did, and expressing that the data from the Phase III studies was positive, which it was.

AMF has zero evidence of such intent. As Your Honor pointed out earlier, the record is clear that Smith and Celgene -- there's no evidence that Smith and Celgene knew there was a single major metabolite or even that Celgene knew there was a single major metabolite as of Smith's April

statement that she couldn't have intentionally or recklessly misled the market by projecting a year-end filing.

As Your Honor pointed out, Smith was informed by Martin just two days before his alleged July statement in writing about both the discovery of the metabolite, a vetted plan by former FDA consultants to address it, and an understanding that neither approvability nor timing were affected by it. There is no evidence that Smith received any information to the contrary.

Your Honor, when you talk about October, nothing changed. AMF does not point to a single piece of evidence sent to Smith suggesting that the plan was no longer valid or that would have given him pause to question whether the plan remained in place. That is in part because there is no evidence that it was not, which makes Martin's October statement that the Phase III data would form the basis of the NDA submission, which the team was working hard to get ready to file by the end of the year, not fraudulent as well.

All of the evidence in Martin's possession, just like in Smith's, suggest that the plan to address the metabolite remained on track and so did the submission. The consultants had vetted the plan; and even more, just days before Martin's statement, he asked his team to confirm that the information in the slide was accurate, which had the year-end filing by 2017 and the positive Phase III data.

Nobody contradicted Martin's slide. Nobody said there was reason for concern. Thus, this is evidence that Martin was not reckless in his statements and did not intend to deceive. It is the only evidence about Martin's scienter.

Finally, AMF's attempts to hold Smith liable for corporate statements or the corporation itself liable for the statements, their imputing Smith or Martin's scienter on the corporation, find no support in the law.

Your Honor, plaintiff has some slides that talk about who knew what when, but these are not Smith and Martin. These are random Celgene other employees. So putting aside that Smith or Martin had no scienter to impute to anyone, there's no evidence that Smith had ultimate authority over all public statements about ozanimod.

Plaintiffs just don't present evidence of such authority, and that is dispositive on whether he can be held liable as the maker of Celgene's statements about ozanimod. Nor is there any precedent for applying the doctrine of corporate scienter here.

Where, as this Court has already held, Your Honor, these statements are not false and there's no evidence of pervasive misconduct. Your Honor held in *Schwab* that these statements are not blatantly false, they're not evidence of pervasive misconduct.

It's not even -- there's no evidence -- there have been

no rulings from the Third Circuit that corporate scienter is even a valid doctrine to begin with; but even if it is, it's used in unique circumstances and those circumstances are not present here.

Finally, AMF has failed to establish loss causation through the April 27th alleged corrective disclosure on ozanimod because it was both inaccurate and failed to provide any new information.

For all of these reasons, Your Honor, defendants should be granted summary judgment on all claims, and I'd like to reserve the rest of my time to respond to plaintiffs' counsel.

THE COURT: Sure. Thank you very much, counsel.

I'll give plaintiff an opportunity to give their opening views.

MR. ZIVITZ: Thank you, Your Honor. Again, Andrew Zivitz from Kessler Topaz Meltzer & Check. I'll be presenting on ozanimod. My colloquy at Bernstein Litowitz, Rocky Kravetz, will be handling Otezla.

Starting with ozanimod, Your Honor, what I'd like to do in light of your preliminary view is to run through April and July and October, identify just select evidence that we've amassed to date, and then briefly touch on the arguments with respect to corporate scienter and loss causation that Ms. Yadava mentioned at the end of her presentation.

Your Honor, we sent over some slides this morning for

the ozanimod slides. There's five of them and I think this will be very helpful in terms of running through what evidence we have for April, July, and October.

Starting with the April slide, which is the first one, here, Your Honor, on April 27th Celgene issued several misstatements and omissions in its Form 10Q, in Form 8K, in conference call slides that were posted on the company's website that focused on two things primarily: submitting the ozanimod NDA by year-end 2017 and promoting data from Phase III ozanimod studies.

The evidence that we have amassed shows that those statements were knowingly and recklessly misleading for failing to mention evidence, evidence of a major metabolite, that the company had at that point in time which posed a risk to the year-end 2017 NDA submission.

We cite to three pieces of evidence on the slide, and let me walk through them if I may.

First of all, on January 12th, 2017, so several months before the April 27th misrepresentations and several months after the mass balance study was completed, the ozanimod team meeting minutes circulated to Jean-Louis Saillot, who is vice president of regulatory affairs and clinical pharmacology and a direct report to Martin, and Jonathan Tran, executive director of clinical pharmacology, flagged the fact that identification of a new metabolite in the human mass balance

study is a risk factor and then recognized from that, if the significant new metabolite is identified, then we will have sufficient -- insufficient toxicology data to support the NDA.

Now, what's important here, Your Honor, is that our expert, our toxicology expert, Dr. Frederick Guengerich, a professor down in Vanderbilt, testified that at this time, January 2017, Celgene had evidence. They had evidence that, quote, there was a defect in the mass balance study which is an indication of an extra metabolite that's not been accounted for. That's in January.

Fast forward, Your Honor, to three days before the conference call and before the 10Q and before the 8K, a presentation was made to Saillot and to Defendant Martin stating that the data from the mass balance study indicated the existence of a new metabolite by stating, quote, it appears this new peak is real. That is evidence of a major metabolite.

The document went on to acknowledge, Your Honor, that Celgene might need to delay the NDA by eight months in light of that because they would have to perform additional studies on the new metabolite.

Another point here, Your Honor, which we lay out in our papers, is the ozanimod team's actions here are probative of scienter. They were scrambling; they were creating project teams; they were ordering studies; they were attending

meetings; they were reviewing data.

That is all indication of knowing a material fact that we respectfully submit they had a duty to disclose to investors. That's what the *Arena Pharmaceuticals* case out of the Ninth Circuit has held -- and we cite this in our own papers -- that, quote, defendants' own response to an issue contributes to an inference of scienter, and that applies here, as well.

I want to say something and I'm going to get back to corporate scienter at the end. We recognize that April is our toughest claim, Your Honor. I will concede that.

But at the same time you have Martin, who is a defendant here, who knew about the metabolite before the April statements. His scienter is imputed to the company. I will get to that in a moment, Your Honor, but let me move on to July briefly to talk about the evidence there, because at this point in time everybody knows that there is a major metabolite.

Here, Your Honor -- and this is on Slide No. 2 of ozanimod, these are the July 27th, 2017, misstatements and omissions, the evidence that supports falsity and scienter for them. Here again the company was promoting submitting the ozanimod NDA by year-end 2017 and, again, promoting positive ozanimod testing data.

But, Your Honor, just a sampling of the evidence listed

on Slide 2 -- and we present a whole host of additional evidence in our papers -- defendants knew by July 27th about the metabolite and Celgene would not have critical testing data before year-end when it promised that it would submit the NDA.

Let me again run through just the select evidence that we have on this slide. It's a continuum, Your Honor.

On June 6 David Wilson, the clinical bioanalytical lead, told Jonathan Tran, executive director of clinical pharmacology, that Celgene needed at least 15 months and potentially as long as three to four years to amass sufficient LTS data, long-term stability data, for relevant clinical studies characterizing the metabolite that was going to be folded into the NDA.

A week later Jonathan Tran takes that information and presents that information to the executive committee, including Martin and Saillot, advising them of several things. Number one, that the metabolite 273 was more potent than ozanimod; that adequate characterization of 273, including long-term stability, is, quote/unquote, required by regulatory agencies; and that the metabolite test results will not be considered validated by year-end 2017 due to a lack of long-term stability data.

Fast forward one month, July 17th, so we're still in advance of the July 27th misstatements by the defendants,

Martin is told, quote, unaddressed, the metabolite would lead to a refuse to file by the FDA and that the NDA could be delayed by one to two quarters.

Then you get to the final piece of evidence that we have on this slide, and this one is critical for purposes of determining scienter for -- or at least creating a genuine issue of fact for scienter as to all of the defendants. It's an internal e-mail chain circulated within Celgene that is entitled "Ozanimod Presubmission Meeting Update. Material Information. Please Do Not Share." That last part, "Material Information. Please Do Not Share" is all in caps.

What this document goes on to say is that the metabolite data is, quote, material information being shared on a need-to-know basis, closed quote; and importantly for our purposes it states in part that the metabolite, quote, has the potential for major implications for this submission.

The most important fact here, Your Honor, for purposes of scienter, the e-mail confirms that Smith, Terrie Curran, Martin, Saillot, Jay Backstrom, the chief medical officer of Celgene; Matthew Lamb, global head of regulatory affairs of I&I; Maria Palmisano, corporate vice president of clinical pharmacology; Gondi Kumar, vice president non-clinical development; and other high-ranking officials across Celgene were aware of this metabolite information.

Again, Your Honor, information that the e-mail called,

quote-unquote, material and was not to be shared outside of Celgene.

We respectfully submit, Your Honor, that that evidence alone raises a genuine issue of fact for the jury as to the July 27th misstatements.

Briefly, Your Honor, I'll move on to October, because I know the evidence becomes even more compelling. In October -- here we have statements on October 26th and October 27th in 2017. Defendants again focused on submitting the ozanimod NDA by year-end 2017 and on positive ozanimod testing data.

But, Your Honor, the evidence shows that the statements were knowingly misleading and incomplete for positively promoting that data and the impending NDA submission but failing to mention anything about the metabolite and again the conceded risk that it posed to the NDA.

Directing your attention, Your Honor, respectfully, to Slide No. 3, what I'm going to do with this slide is I'm going to work backwards. What's critical here is that what happens is on October 27th, sandwiched in between the two statements on October 26th and 28th, Celgene submits what's called a briefing book to the FDA which is a lengthy document about the impending NDA that is riddled with open questions that investors know nothing about.

For example, in the briefing book Celgene expressly

acknowledged that the NDA will, quote, not have included LTS assessments and sought the FDA's permission to submit that missing data after the NDA was submitted to the FDA.

But internally, Your Honor, the record shows that Celgene had conceded previously that the FDA would not consider the study results as quote/unquote validated without the data and that the FDA in March of 2017 told Celgene that it must submit full clinical study reports with the NDA.

Moving back to October 19th, this is a critical piece of information or evidence, Matthew Lamb sends Florence Houn, the vice president of global regulatory affairs and former NDA reviewer for the FDA, so she's familiar with NDAs submitted to the agency -- he sends her a copy of the briefing book and he warns internally, quote, I don't feel the package is ready for submission and that Celgene should wait for ozanimod NDA submission until we've completed the studies.

Dr. Houn agreed, cautioning she saw no legitimate rationale for the company's request to submit the missing data after the NDA review period.

A month earlier, September 18th, 2017, Wilson again sends Dr. Tran information, including a slide deck, confirming Celgene won't have the missing LTS data for between one and five years, depending on the study in question.

Finally, on August 10th, Your Honor, again moving back in time, Dr. Saillot gave a presentation at the I&I regulatory

affairs meeting attended by Matthew Lamb, who was head of global regulatory affairs for the company, warning that, quote, an incomplete clinical pharmacology package can potentially lead to a refuse to file.

Again, we respectfully submit that just this sampling of evidence, Your Honor, supports a genuine issue of fact that should go to the jury.

Your Honor, one point to raise here -- and let me -- Ms. Yadava talked about scienter for Mr. Smith and for Mr. Martin. What's interesting here, Your Honor, is we have company statements. There's two groups of statements.

You have Smith and Martin's statements. There are five of those that are directly issued by them and the rest are unattributed company statements. They're in SEC filings, they're on the corporate website slides.

We established Celgene's scienter in two ways here. Number one, we established scienter for these statements through Defendant Smith's scienter. He was a person with ultimate authority over the corporate statements. We have evidence of that. Because of that, he acted -- because of that and the fact that he acted with scienter as the class period went on, plaintiff has established scienter for those company statements.

Courts have held that authority is an inherently fact-bound inquiry. We cited the *Glickenhaus* case for that

out of the Seventh Circuit. Closer to home there's the *Pfizer* case. The court held the testimony the top management reviewed, all of the press releases which Smith did hear, was evidence from which a jury could conclude that defendants made the statements.

As far as Smith's scienter, Your Honor, several points to make here. He relied on information from Mr. Martin, who knew about the metabolite on April 24th, 2017; he relied on other members of the ozanimod NDA team; therefore, Smith has scienter as well.

Specifically, Your Honor, moving forward into the class period, on July 27th -- I referenced that e-mail at supplemental statement of disputed facts at paragraph 105 saying "Ozanimod presubmission meeting update. Material information. Please to not share," and Smith was informed of that. That document goes on to say that the metabolite, quote, has the potential for major implications to the submissions.

Again, Mr. Smith was informed of that information, according to that document. Smith also received the FDA's November 21st preliminary comments to the briefing book which told Celgene it needed to include the missing data in the NDA submission.

Mr. Smith also received a tracker memo identifying the missing information as, quote/unquote, a refuse to file issue.

I recognize that document was dated November 28th, 2017, but, again, it establishes Smith's mounting knowledge throughout the class period.

The second way, Your Honor -- and I'll finish up quickly after this. The second way in which we establish Celgene's scienter is through Martin and his team and a long list of high-ranking members within Celgene who knew about the metabolite, who knew that additional testing and delay was caused as a result of that need for additional testing.

Let me start, Your Honor, by saying that all of the corporate scienter cases that defendants cite to in their papers are inapposite here because they're pleading cases. The issue in those cases is whether or not the company can be deemed -- an inference can be drawn to show that the company knew about something that was being alleged.

Here, Your Honor, we have evidence following 18 months of discovery that more than ten high-level managers, employees within Celgene, knew about the metabolite. They knew about the risk that that metabolite caused to the NDA.

So because there is evidence, Your Honor, that the most senior executives in the company knew about the metabolite, they collectively chose not to disclose it and instead told the market that it was smooth sailing ahead for the NDA, the scienter of all of those individuals should be imputed to the company.

Second point on this, Your Honor, is that even if the pleading cases cited by defendants apply here, they still support a finding of corporate scienter. Let me explain why.

In *Cognizant*, Your Honor, Judge Walls stated that under any approach to corporate scienter at the summary judgment stage, to prove liability against a corporation, a plaintiff must prove that an agent of the company committed a culpable act with the requisite scienter and that the act and accompanying mental state are attributable to the corporation.

The *Cognizant* court then went on to explain that, if that agent either furnished information to management that is used to mislead investors or tolerated the misrepresentation after its utterance or issuance, that agent's scienter binds the company.

Here, Your Honor, Martin was the president of Receptos. He was the leader of the ozanimod NDA project. He thus furnished information to Celgene's senior management in Summit, New Jersey, that was disseminated in the company's statements or withheld from the company's statements as part of the quarterly disclosure process. We run through all of this in our papers, Your Honor. In addition to furnishing information, he also tolerated the misrepresentations.

Think about it, Your Honor. Throughout the entire class period, the company is repeatedly saying in all of its corporate documents, its form 10Qs, its Form 8Ks that are

going out to the market, the NDA is going to be filed at year-end '17 and the data is good. Martin let all of those statements be issued without correcting them. That is scienter that is imputed to the company.

At the risk of piling on, Your Honor, in addition to Martin, there's an entire core of executives here and officers who knew about the metabolite and the risks arising from it. They include: Terrie Curran, a defendant in this case, the head of I&I; Jay Backstrom, chief medical officer; Matthew Lamb, global head of regulatory affairs; Florence Houn, vice president of global regulatory affairs; Jean-Louis Saillot, who I mentioned earlier; and Jonathan Tran.

All of these high-level managers had responsibility for the NDA. They were not rogue employees that the corporate scienter pleading cases focus on to refuse to apply scienter to the corporate entity.

More to the point, Your Honor, this was a corporate decision. They made public statements about the NDA. They made public statements about the data. They did not once mention the metabolite or the risks arising from it. That is material information.

As -- the document that I showed Your Honor earlier, it's material information as determined by the company that we respectfully submit the jury should make a determination as to whether or not Celgene had a duty to disclose.

Real quickly, Your Honor, on loss causation, defendants have tried this now -- I think four times now. The statement was or the disclosure on April 29th was a Morgan Stanley report.

As Your Honor has held previously, this synthesized detailed information about the metabolite and reported based on that information that the timing and filing of the revised NDA would likely be between one and three years. The stock dropped in a statistically significant fashion in response to the news. Analysts tied the drop to the Morgan Stanley report. That bolsters a showing of loss causation. We cited the B of I case for that proposition. Defendants notably do not point to any other reason for the stock drop on that day.

Your Honor has ruled on this, as I mentioned, three times at the motion to dismiss stage, then based on evidentiary record at class certification, and later in denying defendants' motion to modify the class period.

Specifically, Your Honor held in denying the motion to modify -- and let me read this for the record.

(Reading.)

> It appears more likely than not that the April 29th report provided the market with new corrective information about the metabolite discovery.

Defendants haven't provided any information, any

argument for Your Honor to revisit the Court's ruling. They do contend, Your Honor, that the Geoffreys report that came out several days prior somehow moves the needle here, but Your Honor rejected that argument twice, both at class certification and the motion to modify.

As far as defendants' last argument that somehow the Morgan Stanley report got it wrong, they contend that Celgene did not have to run certain toxicology studies and that the delay did not last one to three years.

It's a faulty premise, Your Honor. Celgene did have to run four non-clinical studies that the FDA relied on in approving the ultimate NDA submission and the -- or the revised NDA was not resubmitted until March 2019, two years after -- more than two years after the original submission, so there was an extensive delay.

Finally, Your Honor, their position misstates the law in corrective disclosures. The relevant inquiry is, quote, not what the facts reveal or not the facts revealed in the corrective disclosure but what those facts reveal to the market.

If the market reasonably believes that the corrective disclosure is true and the stock price reacts accordingly, that is sufficient for loss causation purposes.

Unless Your Honor has any questions on that front, I will yield the rest of my time and let Mr. Kravetz talk about

Otezla.

THE COURT: Before we do, let me ask, Mr. Zivitz, since we're sticking with this -- let me ask you a few questions.

MR. ZIVITZ: Okay.

THE COURT: First, what's your position as to when Celgene confirmed that there actually was a metabolite? What's your date?

MR. ZIVITZ: The date is -- I believe it was in June, Your Honor. As far as -- let me be clear. As far as evidence of a major metabolite -- I want to be crystal clear about this, as I mentioned with respect to April.

In January they see evidence of a major metabolite. Our toxicology expert, Dr. Frederick Guengerich, says at that point in time they knew they had a metabolite that was unaccounted for. As far as identifying the specific --

THE COURT: Fine, but your expert is not a mind reader. He can give an expert opinion, but he can't opine on somebody else's state of mind.

What evidence do you have that they knew it was -- I know you said evidence and I've read it where they say, "If it's a metabolite, we're going to have to do the following" or "We should come up with contingency plans," but I don't have any cases that you've cited to me that they say, "There's a potential issue, let's start coming up with a contingency plan" before they've confirmed what the actual issue is.

Your expert may say, "That tells me it's a metabolite," but their internal documents don't say, "We know this is a metabolite." They say, "It could be a metabolite, and if it is, this is what we're going to have to do."

How do I now say that is something they should have disclosed when they weren't even sure and hadn't confirmed it was a metabolite?

MR. ZIVITZ: Your Honor, let me address it with two points. Number one, the document from April 24th, 2017, which is a presentation that was made to Mr. Martin, stated that the data from the mass balance study indicated the existence of a new metabolite by saying it appears this new peak is real. That is scientific speak for there is a metabolite.

THE COURT: No, it's not, because that same document that you're referring to then goes on to say, "If it is a metabolite, this is what we're going to have to do." You can't tell me that that's scientific speak for something when they then go on to clarify and say, "If it is a metabolite, these are how we're going to have to react to it."

That would be -- Mr. Zivitz, I know you're plaintiffs' counsel. That would be a material omission in your argument that I would need to know, but the fact that -- I'm being facetious.

But the point of the matter is, their internal

documents say, yes, the peak is real and they wanted to confirm it was one peak, a single peak, but then it said, "But if it's a metabolite, this is how we're going to have to address it."

MR. ZIVITZ: Your Honor, listen, I will recognize that the case certainly grows stronger as the class period goes on. As I mentioned at the outset, April is by far our weakest point.

That said, Your Honor, we respectfully submit, and I think we briefed it up very well, that they had material information. All they had to say, Your Honor, was, "We intend to file the NDA by year-end 2017, but we have this data which calls that into question." That's what we respectfully submit investors had the right to know.

But certainly as you get to the July statement, they absolutely 100 percent knew about the metabolite. I went through the evidence, but, again, that piece of evidence right before the July 27 statements, the July 26 and 27th e-mail where Matthew Lamb is writing "Material Information. Please Do Not Share," all in caps.

I mean, that is securities fraud in a nutshell. The company determines it's material information and at the same time says, "We're not going to share it outside of the company," so certainly by July the company knew about the metabolite and knew that they had an obligation to disclose it

and opted not to.

THE COURT: Okay. I understand your argument as to the e-mail that this is material information, share it had on a need-to-know basis, it's confidential. I think confidentiality was mentioned twice in the e-mail chain, but my more specific question goes to defendants' argument that Smith was not aware of that.

I know you made a representation in your slide that Smith was aware of it, but what defendants have pointed to, it's Exhibit 122 submitted to me -- I know you used different exhibits -- but this one of the key documents defendants relied on. It's the July 25th, 2017, e-mail from Martin originally to Curran and then sent from Martin to Smith, and this is what defendants point to repeatedly saying that this is all Smith knew, not only his July statements but also in his October statements.

I just want to know what evidence do you have to contradict that view of defendants?

MR. ZIVITZ: Thank you, Your Honor. So let me walk through this step by step.

With respect to the July 26th and 27th e-mail from Matthew Lamb, just to reiterate, what he says in this e-mail -- again, information that was not to be shared outside of Celgene because it was material, he writes:

(Reading.)

Terri was informed yesterday evening by Philippe and I understand that Gondi Kumar, Maria Palmisano, Jay Backstrom, and Scott Smith have been informed so far. Please keep this strictly confidential for the time being.

He then goes on to say that this has potential for major implications for the submissions.

We would submit, Your Honor, that this document is a countervailing piece of evidence to the July 25th e-mail. As far as the July 25th e-mail is concerned, that document, Your Honor, is subject to different interpretations.

For example, the e-mail concedes that, quote -- it says it in the body of the e-mail, quote, adequate characterization of clinical pharmacology properties for RP112273, the metabolite, is required by regulatory agencies.

They knew that at that point in time adequate characterization required long-term stability of the metabolite and defendants didn't have it. So Smith on the one hand is being told "Don't worry, don't worry," but at the same time is being told the agencies are going to require this missing data.

In addition, Your Honor, it's just one piece of evidence undermined by other evidence that we have included in the record, including this Exhibit 405, which I mentioned earlier.

THE COURT: But I'm just focused on Smith. Part of my difficulty in reading your -- and I'll get to the other statements. I will. I'm just focused on what Smith knew and when he knew it.

He gets this -- it's Exhibit 122. Ultimately, the conclusion is that a lot of work remains to be done in a very short period of time in order to keep the submission on schedule.

He also is told that, "Our plan data should be acceptable to the agency and allow us to keep the submission on schedule."

So in that e-mail, before he makes his July statements, it doesn't -- there's no indication, at least when I'm reading the e-mail, saying that this is at risk now.

I understand what your theory is. Your theory is you should have disclosed that when you were submitting the NDA there was a potential issue. Right? I don't know the precise language, but it was an at-risk submission in light of the metabolite and the lack of corresponding study.

But I'm just trying to focus on what Smith knew and when he knew it. I do agree that you've given me a lot of other information about concerns that were raised in the company by other high-ranking folks at different times, but what about Smith's knowledge?

Outside of somebody saying, "I understand Smith knows

this" -- I mean, I don't know that that creates a genuine dispute of material fact unless you have deposition testimony from that person as to "What was the basis for your understanding?" and you can show a reasonable inference that Smith knew of this. I'm trying to understand what Smith knew and what you can put in Smith's mind before he makes the statements.

MR. ZIVITZ: Your Honor, I appreciate that. The evidence that we put forward is in our papers with respect to Smith. I mentioned the document we were just discussing. I think that the July 25th e-mail is subject to multiple interpretations.

Again, it includes a lot of doubt as to the -- a lot of doubt as to when the NDA will go in. I recognize that it has a representation from Martin to Smith saying that "We should be on track" or "We are on track."

One thing I'll note here, Your Honor, is that the July 27th statements are company statements. There's a 10Q, there are 8Ks, and Martin's scienter is imputed to Celgene for purposes of those statements because, like I said earlier, he furnished information or misinformation to the company and he let those statements go without correcting them.

So even if Your Honor finds that Mr. Smith doesn't have scienter for the July 27th statements, Martin and the rest of his team and multiple high-level officials within the

company -- as I mentioned you have Mr. Martin, Gondi Kumar, Maria Palmisano, Jay Backstrom, the chief medical officer of the company; Terri Curran, the head of I&I, all of these individuals knew. As reflected in the exhibit we were talking about earlier from July 26th and 27th, that scienter gets imputed to Celgene for purposes of Celgene's misstatements. Again, these are company misstatements.

THE COURT: In defendants' briefing, their motion papers focused on the actual statements that were made three times by Smith and one time Martin joined. I didn't really see them address the Qs and Ks.

What are you saying was represented in the Qs and Ks that was a misrepresentation?

MR. ZIVITZ: Your Honor, paragraph 397 of our complaint there's a statement with respect to, I believe, the NDA and the data in the form 10Q. The corporate slides were placed on the company's website, at paragraph 398 of our complaint. And at 399 additional slides are referenced there that were placed on the company website. Again at paragraph 403 of our complaint, Celgene filed a form 8K containing a press release with company statements with respect to ozanimod.

I apologize, Your Honor, I don't have those specific statements at my fingertips, but I will find them.

THE COURT: So you're saying I should look at paragraphs 397, 398, 399, and 403 of your complaint?

MR. ZIVITZ: Correct.

THE COURT: I'm going to give defendants -- I just have to have may clerk pull those specific paragraphs for me. I just want to make sure I have the right paragraphs.

Now I'll hear from your colleague as to Otezla.

MR. ZIVITZ: Thank you, Your Honor.

MR. KRAVETZ: Good morning, Your Honor, Robert Kravetz on behalf of plaintiffs. I'll be arguing the Otezla portion of the case.

Your Honor, this is a triable case as to the Otezla claims. The Court denied the defendants' motion to dismiss the April statement finding it to be an actionable opinion, and the voluminous discovery record has validated that decision, and most of the arguments advanced by defense counsel go to the weight of the evidence, not the underlying sufficiency. That's both with respect to the April statement and the new claim that -- the July statement.

We do have slides in connection with Otezla, Your Honor. My plan is to reference some of them, but I think I'd like to just directly address some of the comments of Ms. Yadava, starting with loss causation, because I think some of the concepts of loss causation are actually helpful when we think about falsity and scienter as well.

As Your Honor noted, the standard in general for summary judgment, the same standard applies to loss causation.

The Third Circuit has held clearly that loss causation is a fact-intensive inquiry usually reserved for the jury, and the test is whether the misrepresentation or the materialization of the risk was a substantial factor in causing the loss.

Under that test, a corrective disclosure need only relate to the same subject as to the misrepresentation. It need not be a mirror image, as Your Honor held in the *In Re: Eros* case.

Here the evidence shows a material issue of fact is a loss causation because the misrepresentations and omissions about Otezla sales guidance and the underlying metrics that produced that guidance related to the same subject matter as to the corrective disclosure.

I indicated that there's a lot of overlap in these concepts, Your Honor. It's really shown in the last three slides of the deck that we provided to the Court.

I think it is helpful to take a step back and just have a very brief understanding in terms of what factors were relevant to setting Otezla's budget and adjusting that budget and the public guidance through quarterly forecasts and what Celgene referred to as the latest estimates or latest assumptions.

Celgene began the budget process in September of the preceding year. It generally was set in December. Once set, the budget didn't change, but then each quarter Celgene would

provide what were known as latest estimates or latest assumptions, which would then inform any updated sales forecasts; and the underlying process and assumption that went into that process were the same.

Slide 9 of our presentation, Your Honor, which is the third from the end, it's just a document -- we have the citations below. These are the building blocks, Your Honor, of the budget and then the latest forecast assumptions for Celgene.

You can see three of the building blocks would be market size or expansion, that's the extent to which the overall market would grow; market share, the extent to which Otezla would capture shares in the market; and then market access, the extent to which Otezla could increase its access of the market typically through entering into managed care contracts to remove step edits.

Ultimately, these building blocks would be translated into a forecast regarding how many units of Otezla that Celgene expected to sell in a particular year, and then like all pharmacy companies, Celgene would track that contemporaneously.

So given how the process works -- and this is where it's related to all of the metrics, Your Honor -- Ms. Curran and the other Celgene executives would know of the impact of the failure to hit a specific metric and what that could have

on the forecast and the guidance.

We cite in our supplemental fact statement, paragraph 36, that Celgene actually scoped the amount of -- quantified the degree to which market size and market share would pose a risk to the budget in the first quarter of 2017 of approximately $140 million. It got worse, and that's only with respect to two of the metrics, market share and market expansion, but it's relevant.

Then the next slide, because this is also addressed in the corrective disclosure, Slide 10, market share metrics were also critical to the managed-care plans and guidance. We cite in our papers that Ms. Curran actually received an e-mail in the fall of 2016 that maintaining a neutral budget upon which the guidance was built in 2017 required Celgene to drive more demand to these managed-care plans in 2017 but that conversely failing to deliver an inflection in market share would risk performing to the currently submitted budget.

That's exactly what happened. This is a document that shows what happened over the course of the year, but we also cited to contemporaneous information in terms of what was happening as to market share in these managed-care plans, which was consistent with what's being shown in the slides.

So why is that relevant to loss causation? Defendants criticize us for relying upon information unrelated to the misrepresentations, which they characterize as disconnected

bad news, but our brief in the statements of fact address at length the specific factors that drove the forecasting and the public guidance.

All of the information regarding market share, market size, market access, and inventory flow into the guidance and the corrective disclosure in this case -- and that is reflected in the next and final slide, Slide 11, Your Honor -- not only touches on those subjects generally but here give specific reference to the underlying drivers of the guidance.

So the reduction in the guidance is attributed to overall market deceleration. It's an inability to execute the managed-care strategy, market share impact in patients previously exposed to another related drug category for psoriasis and psoriatic arthritis, and inventory fluctuation throughout the year.

When you compare that disclosure to the misleading statements from April and July, the misstatements clearly relate to the same subject or at minimum create a genuine issue of material fact as to whether they relate to the same subject matter. Market size, market share, managed-care execution are all essential to the guidance.

We cite to an e-mail Ms. Curran acknowledged that market share generally tracked market size or growth. Defendants claim that there's no relationship between the two, but Ms. Curran herself cited to a relationship in a

couple of e-mails we cited in our papers.

The managed-care strategy itself, as we just saw, was dependent upon driving inflection in market share. And all of these other metrics regarding prescriber adoption, the negative views of physicians and patients regarding Otezla, all of that impacts these particular metrics, including inventory.

Our brief also cites to the expert opinion of Dr. David Tabak, our expert who reviewed multiple analyst reports containing estimates for Otezla sales before and after October. These loss causation issues are typically the subject of expert testimony, which generally forecloses summary judgment, as we noted in our papers.

Defendants haven't challenged or even referenced the expert opinion, and that unchallenged opinion at this stage is, had the market known the truth, it would have adjusted sales estimates and projections earlier in the class period which led to price inflation.

So I wanted to address loss causation first because that was the particular argument that counsel seemed to take the most time addressing in the opening remarks.

Moving back to falsity now, with just some background in terms of how the forecasting process works, as I noted at the outset, we do have a voluminous discovery record here. The Otezla claim is a highly fact-intensive claim, and at

minimum there's a material dispute of fact as to whether Ms. Curran sincerely believed the April statement when she made it. And, as I noted, most of the arguments here go to the weight and not the sufficiency of the evidence.

Defendants didn't address the April statements directly. Ms. Yadava did not address those statements directly in her opening remarks. I would incorporate by reference our briefing and our slides in this matter, Your Honor -- it's Slides 2, 3, and 4 -- and absent specific questions, I'll move on to the additional -- address the additional arguments that counsel made.

THE COURT: Let me ask you, just so I understand your arguments. It didn't seem to me as though you were looking to say her opinion that it was exceptionally strong in the first statement that she made during the first quarter earnings call in response to an inquiry by a UBS analyst, but then you pointed to certain things that she did say that have a factual basis. I know that one of the arguments you had is that she said, "If you look at market share, we continue to grow market share."

I'll direct this to defense counsel, but I have seen the internal e-mails, including her e-mail saying, "We look flat," so I'll direct that to defense counsel.

Tell me your theory about the minimal drawdown. By way of background, both parties seem to agree that because of the

price increase coming in 2017, that I'm guessing the wholesalers built up their inventory in the fourth quarter of 2016. I guess I have a couple questions.

One, it doesn't seem as though anybody was surprised about the build-up of that inventory because of the price change, so what's your argument when she said, "We saw minimal drawdown on inventory"? I just want to understand that a little bit better.

MR. KRAVETZ: Certainly, Your Honor. So it is our argument that it's misleading to say that there was a minimal drawdown in inventory. Whether that's viewed as an embedded false statement of fact or whether it's in prong three in terms of omission liability, there's some overlap between the various categories.

What we have here is we have an inventory starting point in the first quarter that was 20 days on hand. The record shows that was well above the normal range of 10 or 13 days on hand. We cite to that on our papers.

So by the end of the quarter, that metric decreases from 20 days on hand down to 13, which is within the normal range. It's our position that's not minimal or modest, as characterized by the defendants, particularly given the internal documents we have showing that inventory adjustment to get to that normal range was one of the key factors that was driving the first quarter weakness. We also have

testimony from Ms. Curran that she was aware that there were discussions of a significant inventory drawdown, which is different than how it was characterized.

Defendants point to the fact that later in that April call that Celgene and Ms. Curran actually quantifies the inventory adjustment as 35 to $40 million, I believe, but that's really of no moment because the numbers there don't necessarily say anything about the relationship between the inventory and the company's forecast.

Ms. Curran herself said that that number was at the low end of the range, so nothing contextually to an investor as to whether that number is minimal or not is of no help to a reasonable investor.

I'd also note, Your Honor, we cite on our supplemental statement of fact 36 to Plaintiffs' Exhibit 36 and that's a March 24th document in which Celgene indicated that it had a change in inventory assumption as a result of the first quarter drawdown, an assumption that went into the budget. That's at page 367, for the record.

But we also allege that the inventory portion of the statement as a whole is misleading because Celgene itself drew a direct connection between inventory and demand. By reference, we allege this in our complaint, paragraphs 143, 144, and 146; but we show in our papers that there are these internal communications where demand was driving sales

weaknesses and forecast shortfalls, and that lack of demand would be critically important to an investor assessing the ability of the company to attain its sales guidance.

So whether the inventory metric is viewed under the second prong of *Omnicare* as being an embedded false statement or the third because it's not telling the whole truth about how bad things actually were in driving demand and the company itself later in the corrective disclosure attributes inventory fluctuation throughout the course of 2017 as one of the material reasons why it didn't meet its budget, we think that we've educed sufficient facts at this stage with respect to that portion of the claim.

THE COURT: Okay.

MR. KRAVETZ: Your Honor, Ms. Yadava mentioned the puffery and vagueness. I would just note the Court already ruled that the April statement was not vague or did not constitute puffery.

The April statement referred to the key drivers to the company's performance and referenced that the underlying dynamics of the business were exceptionally strong. On page 34 of Your Honor's motion to dismiss opinion, Your Honor rejected the vagueness and puffery challenges.

The arguments in our brief are consistent with the Court's prior opinion. These are not just vague and non-specific expressions of corporate optimism but a

mischaracterization and/or omission of specific metrics in particular subjects and certainly not a basis at summary judgment for a decision related to puffery or vagueness.

Defendants make the same argument with respect to the July statement. I'll just move on to the July statement in terms of the portion of that statement relating to the key performance indicators.

Again, this isn't just a vague expression of optimism like, "I feel really great about the quarter" or "I'm just really excited about sales projections."

As with the April statement, the defendants are touting the strength of key performance indicators. They specifically reference to market share and prescriber adoption. There's no difference between the two statements, the April and July statement, from a legal standpoint and no basis to assert that the July statement should be treated any differently from a vagueness or puffery standpoint. The jury must assess the statement as a whole collectively.

Just finally, Your Honor, I think the last direct argument that defense counsel made with respect to the July statement relates to the statement about market share.

Now, the principal argument that defendants advanced was that Ms. Curran was referring to a chart showing that market share grew over a 30-month period so the statement was in fact accurate. There seems to be a concession now that the

statement is related to the second quarter, not to the preceding 30-month period. But I'll note on Slide 6 we actually walk through the evidence as to how Ms. Curran had conflicting information relating to market share in the second quarter of 2007 *[sic]* in terms of slides that she received, her own e-mails characterizing market share, her deposition testimony, and the fact that she received access to other information showing additional market share indicators as declining.

So, you know, now it seems to be more of a 180, and the argument now is that the July market statement -- I think the argument is it's immaterial because a reasonable investor should have known that the statement was inaccurate if limited to the second quarter of 2017.

Again, this is a question of materiality for the jury. The defendants don't point to any evidence from an analyst or any public reporting showing the import of any prior disclosures regarding market share. There's not any citation to an analyst who said, "Ah-hah, Celgene made a mistake" or "I think they misrepresented something."

So, regardless, asking a reasonable investor to take away a contrary conclusion about market share from a slide that defendant concedes in her deposition that she did not even reference about market growth driving pickup of U.S. Otezla sales which doesn't otherwise contain any percentages

for the prior quarters appears to show an uptick at the end of the second quarter. That's insufficient at this stage. That's an argument that goes to the weight, not the sufficiency.

And I would just note, in conclusion, on the falsity point we did include citations in our papers, supplemental statement of fact 63 in our response to the statement of facts 82, in which Ms. Curran wrote in an e-mail in September, just a month and a half later, where she specifically characterized overall national market share running flat versus increased forecasting -- forecasted in 2017.

Finally, just one minute on scienter, Your Honor. Defendants don't spend much time in their briefing on scienter, other than referencing the standard in claiming that it's a high bar to meet.

The Third Circuit has consistently held that plaintiffs may establish scienter upon evidence that a defendant knew facts or had access to information suggesting that their public statements were not accurate, and that is, if you paint a far rosier picture or offer incomplete or misleading information implying that the insider knowledge was different from what the public was hearing.

That's why there is significant overlap between the falsity evidence when you're talking about opinion-based liability in scienter but certainly -- and we have noted on

Slides 7 and 10, we have set forth all of the evidence relating to scienter. Certainly scienter is a triable issue at this stage, given the information Ms. Curran knew and what she said behind closed doors but did not disclose publicly.

Unless Your Honor has any further questions, I'll conclude my remarks.

THE COURT: Just one question before I turn it back over to defense counsel. I have the disclosure, by the way, in front of me. I believe it's Exhibit 86.

You contend this is an October 2017 corrective disclosure, and you show what it was attributed to. Let me just ask you your overall view as to what it was attributed to: overall market deceleration, inability to execute managed-care strategy, market share impact in patients previously exposed to biologics, and inventory fluctuation.

Just so I understand, you're saying none of this was new information that they received after the second quarter going into the third quarter. That this was information, if properly analyzed, would have shown the direction of Otezla's sales vis-à-vis the forecast.

MR. KRAVETZ: Yes, Your Honor. At the time of the first quarter and of the second quarter, this is information that was known to Ms. Curran and other executives that concealed known risk, that the risk only materializes in connection with the corrective disclosure in October; and,

certainly, information that had it been known at the time would have had an impact on the price of the stock given that once all of this came -- what was known to the market and defendants downgraded the public guidance consistent with the information that they knew going back to the first and second quarter, you had a significant price drop.

THE COURT: The guidance was the change of approximately 250 million, and that was the only drug whose 2017 guidance was changed?

MR. KRAVETZ: That's correct, Your Honor.

THE COURT: Thank you. That's all I have for you. I'll turn it back over to your adversary.

MR. ZIVITZ: Your Honor, it's Andrew Zivitz. I apologize. Can I make one more point on ozanimod since we were talking so long about scienter? There was a piece of evidence that I neglected to mention that I think is important.

THE COURT: Sure.

MR. ZIVITZ: Your Honor, in terms of Smith's scienter and the company's scienter, the one document that I neglected to mention, there was a May 16th, 2017, e-mail that Dr. Saillot sends to Martin imploring him to inform Defendant Smith about the metabolite.

He goes on to say that there are risks from the mass balance study, and he says that the December filing date is in

jeopardy and a best-case scenario and he recognizes that this discovery is, quote-unquote, painful and bad news. Martin responds saying, "We'll talk about it."

The reason why I'm raising this, Your Honor, is whether Martin told him or not, if he chose to hold back the information, Martin's scienter, it's misinformation that is being sent to the company. It imputes scienter for purposes of Celgene's scienter as of the July statements.

So even if Smith did not know at that point in time, even if the only informing that Smith received was that e-mail from Martin -- and I think the other document we were talking about earlier, Exhibit 223 calls that into question -- this is misinformation that as the *Cognizant* courts recognized at the pleading stage, it's the furnishing of misinformation that imputes scienter to Celgene for purposes of the July 27th misstatements.

Thank you for indulging me there, Your Honor.

THE COURT: You're welcome.

MS. YADAVA: Thank you. I'll start with ozanimod, and I'll just start with the point that Mr. Zivitz just made.

That e-mail was, as plaintiff conceded earlier, before the metabolite was identified. Even plaintiffs' counsel itself said today that the metabolite was not identified with any certainty until June of that year, the May 16th e-mail has no relevance to scienter.

Additionally, Your Honor has covered some of the points that I wanted to make about April. It's clear that there is no metabolite as of April.

I just want to point out something that I think -- I'm going to walk through plaintiffs' slide because I think this is their best evidence and I can tell you exactly why it's irrelevant to the --

THE COURT: You're going to use their slides?

MS. YADAVA: Yes.

THE COURT: Just let me know what slide you're on. I have it.

MS. YADAVA: I'm just starting with 1 of the scienter evidence for April. These are what I believe Mr. Zivitz was walking through, and I just want to walk through and explain why they're irrelevant.

I want to point out that what plaintiff has done throughout this case is try to create issues of material facts by just giving us one sentence or one line from an e-mail without giving us the rest. That is, I would submit, disingenuous.

If you look at the January 2017 point from Dr. Guengerich that Your Honor explained, this expert opinion does not change the facts, this does not create a genuine issue of material facts. But when plaintiff cites this, it says there's an indication of an extra metabolite that's not

been accounted for, right, there's evidence that there was an indication.

But Dr. Guengerich says just a few lines later it was not possible to determine from the study's preliminary results whether the data indicated a single metabolite or something else.

So this is what happens throughout the slides, throughout the facts, facts that are presented. They're not the entirety of the fact. We cannot create an issue of fact by presenting half a fact. That doesn't work to defeat summary judgment.

Same thing when we talk about the -- plaintiffs' focused a lot on this --

THE COURT: All right. So I'll apply the 10(b) standard here to oral argument, too. If you're going to make a statement, it's got to be a full statement and no material omissions. Okay?

MS. YADAVA: Okay, Your Honor. That I can do.

THE COURT: Okay. I'll do it across the board. Use the 10(b) standard when you're arguing before this Court.

Go ahead.

MS. YADAVA: I think we've done that, Your Honor. We have tried to put in the rest of the facts that are missing or omitted from plaintiffs' arguments in our reply brief, but I'm just going to emphasize a few.

Your Honor noted that all of the information on the slide says, you know, it appears this new peak is real, if the significant new metabolite is identified, it's all contingency planning. It does not address that any metabolite was found. Your Honor has already accepted that.

But when we talk about Smith's scienter for any of the statements, nothing changes. Smith received an e-mail from Martin on July 25th, Your Honor pointed it out, in which he says approvability is not -- approvability and timelines are not affected by the metabolite.

This is after Celgene had hired outside former FDA officials to come in and look at their strategy, to opine on what they intended to do as their intended plan as to how to address the metabolite and determined that their plan was going to work. Right? They put in place a plan, and there's nothing to suggest the plan ever fell off track.

Mr. Zivitz focused a lot on what Backstrom knew and what Lamb knew and all of these other people at the company, but this is not how corporate scienter works. You can't just take a little bit of one person's scienter and impute them all in the company.

As I said in my opening, corporate scienter should not even apply here. These are not the facts that rise to corporate scienter. When you look at the precedent in the circuit and you look at cases of *City of Roseville* where there

was a price-fixing conspiracy -- and even then the courts said these are not the egregious circumstances where corporate scienter should apply.

If plaintiffs wanted to say there was pervasive misconduct and all of the employees' scienter should be bundled together and imputed on the company, they should have had evidence to support that. There's no evidence that everybody at the company got together, talked about the metabolite, discussed it in detail, and then decided "In any event, we're going to keep going forward, we're going to lie to the market about it, we're going to all each independently approve the submission." Where is the evidence of any of that? There is none.

This is not a situation for corporate scienter because there are no blatantly false statements. "We intend to file the submission by year-end" or "We are going to file our submission by year-end," those are not blatantly false.

Your Honor held that on the very favorable to plaintiff standard at the motion to dismiss we're going to move forward in this case because it could be potentially misleading, but never did Your Honor hold those statements were blatantly false because it can't be and they're not.

This is not a situation where corporate scienter should apply at all. In their papers --

THE COURT: I don't understand plaintiff to be arguing

that. What I understand plaintiff to be arguing -- we can discuss when the knowledge should be imputed or who had knowledge at what time, but I think what plaintiff is saying is at a certain point there were -- folks who were directly involved in the project realized that this was an at-risk submission. Some said it would be okay; others said no. We know with the benefit of hindsight it was an at-risk submission. You got the RTF.

I think the concern is when you're telling the public "We're submitting by year-end," but internally you know this may not go through, you have a duty to disclose that to the investing public so they realize that there is an issue, the FDA may not accept this submission. "We don't have the long-term study on the metabolite" -- which is what the FDA requires -- "although we're going to see if the FDA will give us an exception here."

I think that's the issue, as far as I understand it.

MS. YADAVA: Your Honor, that's not quite what plaintiffs argue in their papers. They say that the scienter of Smith and Martin should be imputed to the company, to begin with, and Smith and Martin do not have scienter.

THE COURT: Martin is different than Smith. You've argued Smith strongly. Martin seems to be very well aware of the concerns with the FDA submission.

MS. YADAVA: Maybe I can talk about Martin then,

Your Honor, because I think -- I feel just as strongly that Martin did not have scienter and I haven't addressed that yet.

Martin's only evidence -- the only evidence of Martin's scienter is the contemporaneous e-mail he wrote in July where he says that approvability is not affected by the metabolite and neither is timing.

That is the only evidence we have of his actual scienter. Moreover, plaintiffs just completely ignore the entire process by which they hired outside experts, outside experts weighed in on the submission.

There's a slide presented to the experts that clearly says there's no long-term stability data that we will have at the time of filing. Nobody said they would give an RTF.

We're not weighing evidence. This is the only evidence of Martin's mental state. He --

THE COURT: There plaintiffs say that when you actually deposed the FDA consultants they said, "We weren't really asked about the long-term stability."

You might have thrown a slide at them and said, "By the way, they passed off on it." And when they were deposed, they said, "No one really focused on that issue for us." So you're kind of like trying to say, "We showed them a slide, they didn't raise an objection, so everybody thought it was going to be okay."

MS. YADAVA: Your Honor, they did not quite say that.

They said they don't remember --

THE COURT: I'm paraphrasing. I don't have the transcript in front of me.

MS. YADAVA: Right. I'm just trying to explain that these experts were deposed years later. They could not remember a specific discussion of the long-term stability, but they do remember being shown the slides, and all of them testified that they did not believe the company would get an RTF.

They were shown the slides, they testified to such, and they said that they did not believe the company would get an RTF. We have multiple consultants who will point that out -- we'll point that out where the testimony says that, but each of the consultants had said very clearly that there was no RTF.

Here it is. I'm sorry. I've got colleagues on the side here.

THE COURT: That's okay. It's a lot of information. I understand they're helping out.

MS. YADAVA: By the way, they're also contemporaneous e-mails at the time which would have been bizarre, right, for Martin to write e-mails saying things like recent feedback from ex-FDA reviewers, which he says in the same e-mail, Your Honor, that you just pointed out, tox, clin, and pharmacy division director level:

(Reading.)

Recent feedback from our ex-FDA reviewers indicates that our plan data should be acceptable to the agency and allow us to keep the submission on schedule."

And Lesko specifically testified in his deposition that, no, he had strong efficacy data and he did not think that they would get an RTF. Jacobson-Kram said he didn't tell Celgene at any point he thought they would get an RTF. None of these consultants testified there would be an RTF, and this is the strongest -- this, coupled with Martin's contemporaneous review of the evidence, shows Martin did not have scienter either.

THE COURT: What about the July 26 going into 27th e-mail chain, the "This is material information, it's need-to-know" and there's internal concerns being raised about how this metabolite is going to play out?

They said they discussed it with Martin: "Jean-Louis has already had a brief discussion with you about this."

Whatever the experts may say, you have other people who are dealing with the project internally pointing out that this could be a real issue.

MS. YADAVA: They're not saying it could be a real issue, Your Honor. I have the e-mail in front of me. All they're saying is that --

THE COURT: Don't even try it. You're going to lose your credibility if you try to tell me it's not a real issue. You can explain it, but when somebody says to flag this as material information being shared on a need-to-know basis, you're going to have a tough argument telling me that's not really what it means.

MS. YADAVA: Your Honor, I'm not trying to tell you what it means. I'm just trying to explain what the rest of the e-mail explains.

Number one, when it says "material information," it's not being sent -- it's not material in the sense of securities fraud. Right? Your Honor --

THE COURT: You can argue that to the jury, okay, what the definition of materiality is. Let's just agree it's important, but go ahead.

MS. YADAVA: Yes. So there's nothing in this e-mail that I see that suggests that they're going to get an RTF. All they're saying is that they discovered a metabolite, they don't want to share this widely because they don't know -- they just don't want to share it widely. There may be a number of reasons not to share it widely, but we know the discovery of the metabolite was not hidden internally within Celgene.

Lots of people knew about it, lots of people discussed it. It would be imprudent for a pharmaceutical company to

discover a metabolite and not discuss what its potential ramifications, inclinations could be --

THE COURT: They didn't discuss it publicly. That's the issue here.

MS. YADAVA: No, but they discussed it internally, Your Honor, and determined --

THE COURT: Doesn't that show that have an issue "We're not discussing it publically" when you're saying this is important information? Doesn't that kind of prove the plaintiffs' point that you acknowledge this is important, "we have to discuss it, we don't know how it it's going to play out"?

So you're saying, "It's important for us to discuss it internally, but we didn't have to disclose it."

MS. YADAVA: Your Honor, I think there's actually a number of instances of that. Not all important information must be shared with the market. If it's important to the company but there's a plan to address it, a plan that has been blessed, expressed to consultants and there is no evidence to the contrary -- all of the cases that the plaintiff point to about saying one thing to the market and having other internal information about it, it all included having feedback from the FDA that that plan was not acceptable.

We have no feedback from the FDA at this juncture, Your Honor. It's simply a situation where they have

discovered a metabolite and they have a plan to address it. These documents do not contradict or pass doubt on whether there's a plan in place to address it. No one is down-playing that the metabolite was discovered by this juncture, by July 27th, but if there's a plan in place to address it, there's no reason for Celgene to tell the market unless they believe it affected their submission materially.

THE COURT: So you tell me there was a plan in place to address it when, after the FDA consultants, according to -- who have already blessed it, we have Matthew Lamb internally saying, "Next steps are unclear to me at this moment. As Amaryllis notes, the team in San Diego seems to be most concerned with having to repeat clin pharm studies such as DDI," et cetera.

So even after the consultants said, "Don't worry about it," you have internal folks at the company saying, "We don't know how we're going to go forward. We're going to push off the FDA meeting for the time being, and there's a concern we may have to repeat the clinical pharm studies which, by the way, FDA guidance basically said, 'You're going to need your long-term studies.'"

So you have FDA guidance telling you what you need. Put aside the FDA consultants. No offense to consultants but I found if you pay somebody enough money they're going to give you whatever opinion you want, so I'm always a little bit

dubious of that type of information.

But internally the people whose necks are on the line with this submission -- because the FDA consultants don't have any skin in this game, the people whose necks are on the line are saying, "Look, this is a concern." Right? We know FDA says we need long-term studies. We know that. We know when you make your submission you ask for an exception to the FDA to rule in the briefing book.

How can you now say, "Well, we had a plan to address it" when everybody said, "We know it's not what the FDA requires and we're going to ask for an exception when we do our briefing book to the FDA"? And the FDA said, "We're not giving you the exception," ultimately.

I'm lost when you say, "This was not an issue, we had a plan." Yes, but it was a bad plan. And you had people saying it may not work, and critically FDA -- you knew the FDA required this for a metabolite and you were going to ask for an exception to what the FDA wanted.

MS. YADAVA: Your Honor, I just have to respectfully disagree. I don't think the FDA said no in November, but coming back to Your Honor's points, this is Matthew Lamb's opinion in an e-mail. It is not Martin's opinion, it is not Smith's opinion.

Only -- Martin and Smith are the only speakers at this time. They are the only ones who are speaking. We could

debate for hours what these documents mean and what I think they mean and what you think they mean, but, Your Honor, Matthew Lamb didn't make public statements to the market. His scienter -- even if he believes that there's an issue here, his scienter does not matter.

THE COURT: No, but the issue is that Martin is the one in charge of this. You tried to -- even though he's the president and COO, you've tried to -- I know it's crazy, these corporate arguments drive me crazy because the highest person always has the least amount of information, according to their attorneys.

Let's say I accept that for a moment, that the person running the ship really doesn't know what's going on because they're not given the material information they need to make a correct public statement. That's basically the argument. I find it frustrating, but that's the argument.

Let's look at Martin. Martin is in charge of this project.

MS. YADAVA: Right.

THE COURT: Now you're saying, okay -- his team members are saying, "We don't know if this is going to work." You're saying, "Well, you can't attribute that to Martin. They kept it quiet from the top guy."

Maybe they did, sometimes people do that. But I don't know how you can say Martin, when he made the statements in

October, shouldn't have said, "By the way, there's a risk that this may not go through because we have a metabolite" -- I don't know how he could phrase it. He could probably do -- I know there's a bunch of euphemisms for that, I don't know how you do it, but corporate speak for like "We have a problem," which usually doesn't sound like a problem but at least when attorneys get ahold of it you say, "Well, it disclosed the problem."

So what do I do with the fact that you are raising these internal concerns? Martin is in charge of it, and it certainly seems as though there was critical mass, no pun intended, saying that this may not go, regardless of what the FDA consultants say.

MS. YADAVA: Your Honor, there are always stark differences of opinion but they do not reveal scienter. Different people on a team can have different views. That does not mean that Martin's was reckless or Martin did not honestly believe the statements he made.

THE COURT: You're right, but I'm not determining that. I'm determining whether a jury will decide that. That's what I have to determine.

MS. YADAVA: Your Honor, plaintiffs have to present some evidence that reflect on Martin's scienter. This e-mail can't possibly reflect on Martin's scienter. It wasn't sent to Martin.

This is the problem with all of plaintiffs' evidence. They keep conflating speakers and people in different roles. If you look at their slide on --

THE COURT: They do it but you do the same thing. You take the highest person in charge of everything and you say they didn't know anything, and I'm like, "Okay." At a certain point, there's a reasonable inference that the person in charge of the project knows what the concerns are being raised in the project.

I mean, to me, that's just -- if I'm running my chambers and I'm working on opinions with my law clerks, there's a reasonable inference I know what my law clerks are working on. But you try to say, "Well, okay, important members of the team were raising like, 'This may not go through, we may have to do the testing,'" and then you say, "But he didn't have any idea of those discussions." It's silly.

MS. YADAVA: Your Honor, I don't think it's silly. I think different people can have different views, and the idea is these are discussed, the different concepts of what the company should do in response to the metabolite.

They all -- even those people, Matthew Lamb and all, signed off on the NDA, so eventually they became comfortable that they had enough information to submit an NDA. Or everybody at every level is in cahoots to submit this NDA they

know is going to get rejected.

THE COURT: Counsel, I know you keep arguing that, but you didn't hear what plaintiff said and you didn't hear what I said. Nobody is saying they knew for certain.

The question is did they know it was at risk when they put it in and they were hoping that the FDA was going to not follow through with their normal FDA procedures in this. That's what needs to be disclosed.

If you're going to submit to a federal regulatory agency and you know this is what they require and you're asking them to have an exception, does that need to be disclosed? That's what the question is. It was at risk and --

MS. YADAVA: Your Honor -- I'm sorry.

THE COURT: I don't disagree. If they knew it was dead, it didn't make any sense. But the question is did they know there was a potential it was going to be kicked back?

MS. YADAVA: Your Honor, under the case law there needs to be a substantial likelihood that they actually believed the submission was not going to be accepted. They don't have to take a pessimistic view.

The case law is clear. Companies are allowed to continue to be optimistic about their prospects. They do not need to disclose everything that happens. If every company had to disclose everything that could possibly put their

submission at risk, the companies would be making disclosures all the time that may actually impact their approvability of the submission by pointing it out.

But here the thing is, Your Honor, they all determined -- there was dialogue back and forth and they determined to submit. The truth is the reason I keep focusing on Martin's scienter and Smith's scienter is not because I'm trying to say that the highest levels of the organization should be allowed to put their head in the sand. I am saying I think we've gone far off track of who the speakers of the statements are and it is their scienter that matters and their scienter only under the case law.

Under the standards for securities fraud, there has to be scienter of the speaker. Martin didn't receive this e-mail, and it's not an issue for the jurors to decide whether he should have had scienter in the absence of seeing this e-mail because plaintiffs have to provide evidence to create an issue of material fact, and this is not evidence of Martin's scienter.

THE COURT: So you're saying there's no evidence that Lamb testified he shared his concerns with Martin?

MS. YADAVA: No, Your Honor.

THE COURT: None at all?

MS. YADAVA: Off the top of my head, I don't believe there is. But even if there was, Your Honor, let me just

reiterate my point from earlier. People can have differences of opinion and it does not make the speaker's mental state change.

THE COURT: March 15th, 2018, after the fact but it goes to what we knew beforehand.

Lamb: The FDA repeatedly stated what they expected. It was ignored and we got the RTF.

So it's after the fact but it's talking about what we knew beforehand. "We knew what the FDA wanted, we ignored it, we got the RTF." He doesn't say, "I ignored it." He says, "We ignored it. We got the RTF."

I know he's talking probably about Celgene in general, but obviously companies need people to work. So if I'm looking at an after-the-fact omission saying, "We ignored what the FDA wanted. We got it rejected," then you're going to say Lamb never shared that concern with Martin.

MS. YADAVA: Your Honor, these e-mails are all Monday morning quarter-backing. I think we can accept --

THE COURT: Monday morning quarter-backing is like -- he's saying, "This is what we knew beforehand and we ignored it and we got an RTF." We can look at what somebody says about the past to determine what was their state of mind then. If they said, "I knew this was going to happen and we discussed this," that is not Monday morning quarter-backing. That's saying, "Hey, this was a risk we knew about, we ignored

it, and we got rejected."

MS. YADAVA: Your Honor, Lamb also signed off on the submission. This is what I can't -- there's a dichotomy between this that doesn't suggest --

THE COURT: Yeah, corporate pressure. I get it. I get corporate pressure. You've got to get it filed. "We have the FDA consultants, we think we'll get it through, all right, sign off on it."

I get it. I understand corporate dynamics and pressure to get things done. I got that. But when somebody is now saying after the fact, "We discussed this, we didn't do what the FDA wanted" and so forth, that's a genuine material issue of fact.

I'm not saying -- I don't know how it's going to come out. You can raise an argument and say Lamb signed off on it. That's an argument. They can say Lamb signed off on it but he knew that this was going to be a problem. That's an argument.

The jury may agree with you, they may agree with them. I don't know. I'm just looking if there's a genuine dispute of material facts.

You want me to start weighing in on these facts and ruling in your favor. I don't do that. You may wish -- I'm not saying you're going to lose. I'm just saying does this get past summary judgment.

MS. YADAVA: Your Honor, I think when you talk about

things like corporate pressure and all, I understand that there's a backdrop we can overlay, but there's no evidence in the record of any of that. There's no evidence --

THE COURT: Stop. Revlimid was running out. That was their whole theory. I always think of "The Devil Went Down to Georgia," right, because he was in a bind because he was way behind.

Revlimid is running out, you overpaid for three drugs and none of them worked out the way you thought. None of that is securities fraud. The question is, on two of them did they get to a point where you knew there was a problem and then you didn't fully disclose to the market.

Everybody knew Celgene had one big product, Revlimid, and the patent was running out. Look at your numbers for Revlimid compared to everything else. To say there wasn't corporate pressure just ignores the realty of what Celgene was facing as a company.

There was corporate pressure. There's not a doubt in my mind that there was corporate pressure. "We need to get new drugs in the pipeline to make up for the shortfall for Revlimid."

What else was Celgene going to do once Revlimid went off patent if they didn't have anything to supplement that amount of money?

MS. YADAVA: Your Honor, even taking that there was

corporate pressure for a second, filing a sloppy submission or a submission that people thought had a very high likelihood of rejection, which is what Your Honor had said before, doesn't help replace the revenue from Revlimid. But I hear you. Your Honor doesn't agree with my --

THE COURT: When you're under pressure, you do things you shouldn't do. Talk to your associates about their billable hours. People do things they shouldn't do when they're under incredible pressure.

We see that in the law. We talk about "Take care of yourselves." Right? "I billed 3,000 hours." It's like, okay, there's a pressure there that has nothing to do with what we learned in law school.

There are pressures, right, but the big pressure is, "Are we going to keep this organization going forward," and if so, "How are we going to do it?"

Unless I'm missing something, even on that when they changed the guidance, it was -- at that point in time Revlimid was 8 billion and the total revenue was 13 billion. It certainly seems as though they needed to come up with a way to make up that revenue.

MS. YADAVA: Your Honor, even if I accept that, which I will for Your Honor for the purposes of this argument --

THE COURT: You don't have to accept it, but that's a fact. I just read it to you. That's a fact. You don't have

to accept it. That's okay. You can tell me Revlimid wasn't that important to their portfolio. That's fine.

MS. YADAVA: I'm not saying that, Your Honor. All I'm saying is that the corporate pressure -- everyone who had to have signed off on the submission had to have believed that in the face of corporate pressure they were all going to buckle and all agree to the submission, but that doesn't even matter because the only speakers of the statements are Smith and Martin, unless we're going to apply corporate scienter, which should not be applied in this instance. There's no difference between the *Schwab* theory of corporate scienter and this one.

THE COURT: That's a fair enough point. Let me ask you on that point. I read the cases on corporate scienter. I realize it's a very difficult standard to reach.

Let me just ask you, though -- I know that plaintiffs also argued ultimate authority. Let me ask you, though, real quick what about -- I just focused on the statements based on your briefing.

What about plaintiffs' argument that the 10Q -- that's the July 27 10Q and that's a July 27 phone call. I went back to take a look at what plaintiffs pointed to in their complaint, but those seem to be July submissions.

Let me ask you generally, though, if they were going to point to an SEC filing, whether it be a Q, a K, or some other filing, what would be your view as to whether there was a

materially false statement or omission in the filing itself and who would be responsible for it.

MS. YADAVA: Your Honor, I don't think there are materially false statements in the filings, but in any event --

THE COURT: You might be right about that, but I'm just trying to figure out legally who could be responsible.

MS. YADAVA: Alison Kellogg signed the 10Qs and 10ks and you dismissed them as defendants in the first round of briefing.

THE COURT: Okay. All right, folks --

MS. YADAVA: Otezla?

THE COURT: We've got to talk about Otezla. Here is my issue with Otezla: Just to give you a smattering of examples -- and this is Exhibit 50.

Terri Curran writes: "Feedback, reference BOD deck. Don't like market share slide as it looks flat." Then she says, "Can we switch it to what we used historically?"

MS. YADAVA: Yes.

THE COURT: Then Exhibit 54, which is an EBR presentation in April of 2017, it says, "Q1 Otezla market shares relatively flat in both PsO and PsA." Those are the two different psoriasis that you've given me the abbreviations for.

I'm just trying to say that once she says, "We're

growing market share," just using that one as an example, but she's internally saying it looks like it's flat and there's another presentation saying they look relatively flat, using that as an example, why wouldn't that create a genuine dispute of material fact?

MS. YADAVA: Absolutely, Your Honor. I'm happy to address that.

Number one, if you look at that e-mail carefully that you just read to me, the first one about the feedback, she received feedback on a graphic that the slide -- the image in the slide looks flat. She's got her opinion. She's saying "feedback says." We don't refer to our own feedback in the third person.

It says she received feedback from someone else. This is a perfect example of plaintiffs pointing to e-mails and trying to ascribe them to Terri Curran's scienter when they're not indicative of her scienter at all. That's number one.

THE COURT: Wait a second. It's her e-mail and she's saying the feedback looks flat. So she disagreed with that statement? If she did, then why is she asking to change the slide deck?

MS. YADAVA: Your Honor, because the graphics -- they're talking about the graphics for the slide presentations. You've seen probably the market share slide that was presented alongside her earnings call statement.

She's not happy -- someone, whoever is giving her the feedback, is not happy with how the graphic looks. It does not say anything about what she believes about market share. I will tell you the best thing --

THE COURT: Wait a second. It's her e-mail. She's conveying what people -- she doesn't say, "I disagree with it" or "Leave the slide as it is."

How can you say that doesn't say anything about what's in her state of mind?

MS. YADAVA: Because I don't think she's saying that she -- I don't think she's saying that the market share is flat or that anyone else is saying market share is flat. I think they're saying that the graphic -- the way that the graphic on the slide looks is showing market share is flat. They want to change the graphic because it's not looking good, but it's not looking good consistent with the data.

THE COURT: Because it's flat and they want to go back and use a historical analysis because it shows it's going up. The point is she says it continues to grow when internally she's been told it looks flat, and then they have a presentation that says it's relatively flat, but she says it continues to grow market share.

MS. YADAVA: Your Honor, three points in response. One, if you look at my reply declaration Exhibit 13, it is the contemporaneous e-mail that underlies her presentation from

that date. It's three days before.

It shows their numbers that they received at the time on market share and it shows that market share had gone up that quarter from 22.7 to 23.4 percent. That is an increase.

I will tell you, as we have said in our papers and as the only piece of evidence in the record shows, Terrie Curran was referring to market share in her statement over a two-year period.

THE COURT: No, no, no. That may be what the slide said, but she said, "It continues to grow." She's talking about the current time. She didn't say, "Historically we have grown since back in 2016." Her statement was that it continues. It's an ongoing basis.

MS. YADAVA: She testified she was meaning over time it continues to grow. But in any event, the data that underlies her slide, the data she received three days before says market share has gone from 22.7 to 23.4 percent, that is an increase. That is the only evidence of what market share was at that actual time.

THE COURT: No, it's not. She has a document saying it's flat. That's Exhibit 54, the EBR business summary. Quarter 1 Otezla market share is relatively flat in both PsO and PsA. She has other information, as well.

MS. YADAVA: Your Honor, the same slide that you're looking at, Plaintiffs' Exhibit 54 -- is that correct?

THE COURT: Yes.

MS. YADAVA: The same slide shows that it increased from April -- it says PsO market share increased from 20.5 percent in April of 2016 to 23.4 percent as of March 31st, 2017. So even if we're talking about a shorter time period, this is why I'm saying a cherry-picked slide -- I know Your Honor has said that we're doing the same thing but we are not.

THE COURT: It's not cherry-picking a slide. It's just that there's other evidence against what you're telling me. That's what I'm looking at. I'm like, you're saying this is what she was relying upon.

They're saying she had information saying it was flat, and now you want me to make the call. That's not what I do. You can argue and say, "Well, it actually did" -- whatever your arguments are, it was over a longer period of time, it was actually increasing here and so forth. And they can say, "Guess what, her information was it was flat. She said it continues to grow." That's a genuine dispute of material fact that the jury makes the call on.

MS. YADAVA: Your Honor, all I'm saying is saying that it's characterizing it as relatively flat but also have the underlying data in the presentation itself -- this is an opinion statement Your Honor has already held, so it has to be that she didn't honestly believe her statement or one of the

other *Omnicare* prongs.

Here there's data that she received three days before her presentation that shows market share increasing. If a reasonable investor had believed that she was referring to market share over a shorter time period or a bigger time period, it doesn't matter because that does not show that Curran had the intent to mislead the market or that she was grossly reckless in her statements.

THE COURT: So what changed from Quarter 1 to Quarter 2 in her statements that caused you then in Quarter 3 to change your projections? It had to be -- I guess what you're saying is it had to be new information after Quarter 2 that they had in Quarter 3 to downgrade.

So what new information did they get after Quarter 2 to explain why they were changing their forecast?

MS. YADAVA: Of course, Your Honor. As Celgene explained to the market, the market didn't grow as much as Celgene had expected it to. It has nothing to do with market share.

Plaintiffs focus a lot in loss causation about market share and market growth somehow being intertwined. Those are distinctive metrics. One can rise without the other; one could fall without the other as well.

Loss causation means you have to reveal the falsity of something that was said. There's nothing in the record that

shows that those are the same metrics.

THE COURT: Okay. Exhibit 36, 3/24/2017 e-mail explaining why you didn't hit your Quarter 1. Demand. Market growth has slowed down.

It certainly seems as though she knew that the market growth slowing down wasn't new information because she had it back at that time.

MS. YADAVA: That was market growth in Q1. They were predicting market growth in Q3 to grow that it didn't. Q1 we know was a bad quarter. Everyone admits it. Celgene publically explained --

THE COURT: No, no, no. You're saying what changed was -- you've been arguing there's a difference between market growth and market share. I understand the difference in market growth and market share.

You're saying she only talked about market share even if market growth was declining. You said now in Q3 we have market growth declining. She knew in Q1 market growth was declining and that's the key point.

You said there's no evidence that they knew of that. She knew it.

MS. YADAVA: Your Honor, that's not what I intended. What I'm trying to explain is that in Q2 the market did grow. When she made her statement, there was market growth. In Q3 the market did not grow. That's the information that changes

between Q2 and 3. The market did not grow as much as what was predicted.

So the issue here is that -- this is why -- you know, Mr. Kravetz said it keeps going back to loss causation. She's opining in Q2 about why she believes net sales will rebound. She says, "Based on the run rate from Q1 to Q2, here is why I think net sales will rebound," and she points to all of the factors.

What happened in Q2 and what she believes is going to happen in Q2 is not directly related to what happens in the corrective disclosure in October in Q3. One is not revealing the falsity of the other.

They could still have been on track in April, based on the metrics and the guidance she got from others at the company, but they were on track to hit their guidance at that time but circumstances can change, which is exactly what Celgene explained to the market in October.

"Circumstances changed. The market did not grow as much as we thought and the discounts tied to managed-care strategy affected our overall numbers more than we expected."

THE COURT: I need to rule on this motion, but let me just give both sides an opportunity to give me their closing arguments. I'm going to take a 10-minute break and I'll come back and rule.

(Recess taken.)

(All parties present.)

THE COURT: Okay, counsel, let me hear -- I'll give everybody -- I'll give defendant -- I'll give both sides five minutes to give me their closing. I'll let plaintiffs decide how they want to split among counsel, and then I do have to get the ruling going.

Let me hear first -- let me go right in order. Ms. Yadava first, Mr. Zivitz, and then Mr. Kravetz. Before I go any further, I want to thank everybody. I know we have to ask the pointed questions, but I greatly appreciate the preparation of all counsel and the submissions. It was a very big record, but stepping back from my role of deciding this motion, I want to thank counsel for the excellent work in this case.

I'll let Ms. Yadava go first.

MS. YADAVA: Thank you, Your Honor. I think I'll be less than five minutes.

THE COURT: Okay.

MS. YADAVA: I'm just going to emphasize a few points, beginning with ozanimod.

Your Honor, corporate scienter is not available in these circumstances. Plaintiffs continue to point to cases like *Cognizant* where the facts and allegations were entirely different.

There was alleged a criminal bribery scheme, there were

indictments and the like. Nothing of that sort is alleged here. In fact, there weren't even blatantly false statements. Even if the corporate scienter doctrine were to apply, it requires a culpable act by someone with scienter. We don't have that in this situation.

Similarly, Your Honor, we talked about scienter and differences of opinion within the company, but the truth is all that this was and the record evidence shows were differences of opinion within the organization. The case law is clear that differences of opinion do not establish scienter.

Your Honor, you mentioned earlier a hypothetical about your law chambers, and I was thinking about there are law clerks who are working with you on an opinion and they exhibit dissenting views. It doesn't necessarily change your mind state. It doesn't make you think something differently than you thought initially.

So here, Your Honor, there's nothing other than dissenting views that do not reflect on any of the individual speakers' actual mental state.

On Otezla, I'll make two final points, beginning with loss causation. There is a clear disconnect between the contents of the statements in April, the contents of the statements in July, and the alleged corrective disclosure.

The alleged corrective disclosure addressed what

happened in Q3, what happened such that Celgene was no longer able to meet its guidance. It does not address what was happening in terms of run rates between Q1 and Q2 and it did not address market share and prescriber adoption in Q3. There is an entire disconnect between those two.

Your Honor has said himself in the *Aurora Cannabis* case, contrary to what plaintiffs keep saying today, that this is an issue for the jury. There are circumstances when it is not. There are circumstances in which the analysis is clear that loss causation does not apply and that is one of these instances.

THE COURT: Let me just ask you on that issue, though, whenever a company misses earning statements, unless there's something criminal that occurred, as you pointed out -- I'm not saying this is criminal. This is a civil case.

But do companies when they miss earnings statements ever say, "Hey, by the way, what we told you in our other two quarters, you know, that wasn't right"? It's one of those things it seems to me you would never have loss causation under your theory because the company is going to say, "We missed our earnings statements, we're going to have to downgrade, but it's for new reasons."

It seems to me you're saying almost as a matter of law there can't be loss causation in this case.

MS. YADAVA: I'm not saying that, Your Honor. I'm

saying that the reasons that Curran articulated in Q2 for a rebound in sales between Q1 and Q2 that showed net sales on track to meet the guidance are different than what happened in Q3.

There's a lot of case law out there that explains that just because a company does not hit its guidance does not make all statements about that guidance or about those sales fraudulent, and this is exactly one of those instances.

THE COURT: I don't disagree with that as a proposition of law. I'm just saying that plaintiffs' view is -- in their view, the material misstatements or omissions earlier, if she had told accurate, those also contributed -- let's say just contributed. I don't want to say necessarily a sole cause but contributed to why they had to change their guidance. The reason I point that out is it seems like that's a question of fact for the jury to decide as opposed to as a matter of law.

MS. YADAVA: I don't think so, Your Honor. I think in October the corrective disclosure has to reveal some falsity of those alleged misstatements, and when they are apples and oranges comparisons that do not line up -- *Goldman Sachs*, the new Supreme Court case, talks about a mismatch between the alleged misstatements and the corrective disclosures.

This is similar here. They might both be about sales but there is a mismatch between what they are talking about in terms of sales and the underlying metrics.

THE COURT: Okay. Thank you.

MS. YADAVA: Of course. My final point will be on scienter for Otezla.

I know Your Honor thinks there's a lot of evidence in the record that may show a question of fact about falsity, but even if reasonable investors took Curran to be meaning something else than what she said she was intending to say, plaintiffs have to show that it is an extreme departure from the standards of ordinary care.

In the Third Circuit, this is an extremely high bar. They have to show not just that she disregarded other people's opinions but that it was entirely reckless to go forth making a statement to the market about run rates out of Q1 into Q2 and to make a statement about what market share and prescriber adoption are doing in the face of the charts that were also presented at the very same time, which I think negates the inference of scienter as well.

For all those reasons, we believe that defendants should be granted summary judgment in its entirety.

THE COURT: Thank you, Ms. Yadava. Very good job arguing. Thank you.

MS. YADAVA: Thank you.

THE COURT: Mr. Zivitz.

MR. ZIVITZ: Thank you, Your Honor. Thank you and your team for all of the time you guys have spent on this. We

recognize it is in fact a massive record and obviously a lot of time.

THE COURT: I wouldn't mind. My hourly rate is just a lot lower than yours. That's what it is. Go ahead.

MR. ZIVITZ: Your Honor, we have covered a lot today. I will be brief. The very fact that we have been going for two hours, the amount of paper that is before Your Honor, you can tell that -- at least our view, Your Honor, respectfully is that issues of fact abound here with respect to ozanimod.

I just want to read something that Your Honor held at the motion to dismiss stage, just to launch into my last point, which is you held at the motion to dismiss:

(Reading.)

> To make the public disclosures concerning the NDA legally accurate, Celgene -- Celgene was required to also disclose meaningful information as to the metabolite vis-à-vis the NDA.

Our position, Your Honor, is that Celgene is its people. Right? I listed them earlier. I think it's worth listing them again.

At various points in time throughout the class period and certainly by July, you have evidence showing that Smith, Terry Curran, the head of I&I; Martin, Saillot, Jay Backstrom, the chief medical officer; Matthew Lamb, the global head of regulatory affairs; Maria Palmisano, corporate vice president,

clinical pharmacology; Gondi Kumar, vice president non-clinical development, and other high-ranking officials knew in the company about the metabolite and they knew of the risk that arose from the metabolite.

As that July 26 and 27th e-mail recognized, this has potential for major implications for the submissions. This was a material omission that the jury should be able to determine whether the company had a duty to disclose.

Your Honor, just getting back to the Celgene point -- I want to be precise on this. There are SEC filings throughout the class period. Starting in July there's a 10K, there are multiple 10Qs, there are 8Ks containing press releases, there are corporate slides published on the company's website. They are all corporate statements.

As I mentioned, a corporation operates by its people. Martin and the list of folks I ran through, their scienter is imputed to the company for purposes of those statements.

I know Ms. Yadava focused on the *Cognizant* and *Roseville* cases. First of all, again, those are pleading cases.

Here we have hard evidence of actual knowledge by upper-level management. And even under the *Cognizant* test, Your Honor, all of those individuals furnished misinformation to management and they tolerated the misstatements after they were issued.

That is the test under all three tests that *Cognizant* lays out for purposes of imputing scienter to the company for all of the statements.

So, Your Honor, I know we talked about April. Again, I'll concede that April is the weakest of our grouping of statements, but certainly by July you have a host of high-level management that knew about the metabolite, knew about the risk.

Their scienter is imputed to Celgene for purposes of holding those statements in. And those statements, frankly -- you know, based on, as Your Honor noted the standard, there are genuine issues of fact here. So we respectfully submit that those statements certainly should go to the jury.

Your Honor, again, thank you your time. Unless the Court has any questions, I'm done.

THE COURT: No. I'm good. Thank you.

MR. KRAVETZ: Your Honor, Robert Kravetz on behalf of plaintiffs. I have nothing further on behalf of Otezla. I appreciate having the opportunity to appear in front of Your Honor. Thank you.

THE COURT: Thank you.

For both counsel, too, Mr. Kravetz and Mr. Zivitz, thank you for doing a very good job.

MR. KRAVETZ: Thank you, Your Honor.

THE COURT: Before I get to Otezla, I just want to

acknowledge some of the standards that counsel have been referencing but that I'm using to review the current matter.

There was a dispute in the papers as to the standard I should apply as to opinion and whether the *Omnicare* standard applied. Just by way of background, the standard before *Omnicare* was an opinion was not actionable unless it was not honestly believed and also lacked a reasonable basis.

Omnicare changed. It did so in the Securities Act, section 11 of the Securities Act. The defendants are correct that the Third Circuit has not formally adopted the *Omnicare* standard to the Exchange Act. They reserved on it.

The case that most people cited to -- and I'm going to spell it because I have difficulty pronouncing it -- is J-A-R-O-S-L-A-W-I-C-Z, 912 F.3d 96, Third Circuit, 2018.

The reason the circuit did not decide whether the *Omnicare* standard applied was because they said, "Even if we did apply the *Omnicare* standard, plaintiffs still fell short," or at least that portion of the opinion, because it went up on appeal again. That's at 962 F.3d 2020.

Now, in that case, the circuit just said -- without saying it was deciding, it said that *Omnicare* provided the relevant framework as to evaluating opinions.

So under the *Omnicare* standard, opinions are actionable if the statement falsely describes speaker's own state of mind, the opinion includes untrue embedded statement of fact,

or the speaker admits material facts about her inquiry into or knowledge concerning a statement of opinion and such facts conflict with what a reasonable investor would take from the statement.

As to scienter -- I know that Ms. Yadava mentioned the standard, but let me just make clear it's a knowing or reckless standard. Knowing is that you knew what you were saying was false or misleading. Recklessness has to be more than simple or inexcusable negligence. It has to be extreme departure from the standards of care which presents a danger of misleading buyers or sellers that is either known to the speaker or so obvious that the actor must have been aware of it and it does approach conscious deception.

Now, turning to Otezla briefly, because the parties are well aware of the facts. But at the relevant time Ms. Curran was the president of worldwide markets I&I for inflammation and immunology until April 1st of 2017. She then became the president of Celgene I&I and the chairwoman of the IIEC, the Inflammation and Immunology Executive Committee.

I've used a couple of definitions that I would like to make clear on the record. PsA, which is psoriatic arthritis, and then also PsO, which is plaque psoriasis.

The two statements that are at issue, the first concerns April 27th of 2017. Ms. Curran was on a first quarter 2017 earnings call and there was also a press release.

I believe at that time the sales -- the sales were obviously down. That was the reason there were questions asked. I believe it was 21 percent less than Otezla net sales for the previous quarters which would have been the fourth quarter of 2016.

The statement at issue came up because a UBS analyst asked about whether sales would bounce back or whether they would see continued pressure in the near term. The parties have the statement.

Some of the key points of the statement by Ms. Curran was that she found that there were really three key drivers to the performance in the first quarter. First: "Contraction in the market as we saw increased GTN, gross-to-net ratio, as a result of contracting, but importantly that really gives us access to double the number of insured lives going forward."

And she also said, "We saw minimal drawdown of inventory."

She said, "If we look at the underlying dynamics of the business, they are exceptionally strong. If you look at the market share, Otezla continues to grow market share."

I want to make clear that when I'm looking at this evidence I'm just trying to determine whether there is a genuine dispute of material fact. I am not weighing the evidence, I'm not making credibility calls, but I'm trying to determine whether this should get to a jury. I don't know

what the jury is going to do.

We talked about -- I have the deck here, which Ms. Yadava said is Plaintiffs' Exhibit 50. On April 14th, 2017, Ms. Curran writes an e-mail in which she writes: "Feedback, reference BOD deck. Don't like market share slide as it looks flat. Can we switch it to what we used historically?" which is ultimately what did happen.

Defendants are free to argue, "Well, that wasn't really her view. She was just a conduit of information," but at the same time plaintiffs are free to argue that she put it in an e-mail, she thought it was important, she was the one giving the presentation, and she didn't say she disagreed with that statement.

The point is is that it does look flat. And then Exhibit 54, right, so you have the April 2017 -- you have an internal statement that Q1 Otezla market share is relatively flat in both PsO and PsA.

Again, defendants are free to argue, "Yeah, but it was technically true. They said 'flat,' didn't really mean 'flat,'" but to me that's a traditional dispute that goes to the jury as to "When you said 'flat,' did you mean flat or not really flat?"

I'm not being facetious here. Sometimes people use terms and they say, "Well, I didn't really mean we didn't grow. We did grow a little bit, but it wasn't what we were

expecting."

I'm not at all being dismissive of defendants' arguments. They may prevail on that point. Plaintiffs may prevail on that point, but the point is there's an issue there that I think would be appropriate for the jury to determine as opposed to trying to do it on summary judgment.

That's what I did when I went through this file. When she said she saw a minimal drawdown in inventory, plaintiff has an explanation, that Ms. Curran was talking about the total of inventory drawdown and so forth, as to what she meant. I'm sorry, defendant set up an explanation there.

Plaintiffs have a different view. They point to evidence that actually that wasn't accurate. The first six weeks of the year inventory drawdown to mid-single digits, days on hand, again saying that's within the realm of normal. I believe that was Exhibit 67.

But the point being is that there is contrary evidence to what Ms. Curran said at that time and those are generally contemporaneous documents that were not only available to Ms. Curran but Celgene at the time.

The underlying dynamics are exceptionally strong. Exceptionally strong, I do agree, is a puffery term, but the underlying dynamics is not, in my view. Now, of course, you know, that is open to interpretation where defendants can say, "This is what we meant by underlying dynamics." And

plaintiffs can say, "This is what the underlying dynamics are."

But, again, looking at I believe Plaintiffs' Exhibit 67, 54, 64, there is a genuine issue of material fact as to whether or not the underlying dynamics -- I don't know if you could say exceptionally strong, strong, but were they somewhere in that realm of what she was describing at that point.

She also said, "Seeing net sales rebounding and on track with 2017 guidance." There was evidence Q2 was better, that net sales were better, but what plaintiffs point to are exhibits and internal documents where they were saying, "We are bouncing back, but we are still not increasing to the level to make up the first quarter shortfall."

Then there's that question as to were you actually going to be able to make up the shortfall. I don't think anybody disputes that net sales were better in the second quarter. The question is were they good enough to hit the forecasting budget. That would be a genuine dispute of material fact.

Ultimately, once I find that there are genuine disputes of material fact, it's very hard for me as a judge to start ruling on scienter as a matter of law because now I have to determine what was going through her mind when she said that.

Plaintiffs may be right -- defendants may be right. At

most it was simple negligence, which in case they're not actionable. But defendants *[sic]* may be right, this was reckless disregard of the information.

Ultimately, the jury is going to be given that instruction, and that's what the plaintiffs are going to have to prove if they want to succeed. But to do it as a matter of law -- you know, I just say this as an aside and I only say it because I know Mr. Cecchi and Mr. Lustberg and I know their practices, but I read the argument where, you know, "Well, Ms. Curran testified that it was an honestly held belief and so that's all there is to it."

I just thought of Mr. Lustberg in my prior life that if it were only that easy in securities fraud criminal cases to say, "We didn't have the intent to defraud and Rule 29, Judge, in our favor," but it's very difficult on the record to try to determine what was going through her mind at that time.

I do agree that the Third Circuit said this is generally going to be an issue of fact for the jury. That just comes from a different world because it would make defending fraud cases a lot easier if your client could just say, "I didn't intend to defraud anybody," and you're like, "Okay, let's get out of here."

Unfortunately, we know that's not the way it works for criminal defense counsel. This is not a criminal case. I want to make that clear. I don't see any evidence of

criminality here. I'm not trying to suggest it. That was just by way of analogy.

Similarly as to loss causation, I believe it's an issue of fact for the jury to decide. I know that the defendants -- "These are the reasons why we had to change our guidance."

Plaintiffs have given evidence saying, "No, there were other reasons that you knew about when you made the first statement at first quarter and the second statement in the second quarter, and those were contributing factors if not the factors" -- I could see how they argue it to a jury -- "as to why you had to change your guidance."

Ultimately, if defendants are right that nothing that Ms. Curran said, even if it was incorrect, impacted why they had to change their guidance, the defendants prevail because plaintiffs did not prove loss causation.

But if plaintiffs are correct that these were contributing factors or the factors or whatever it may be, then they prevail. But that's their burden and that's what they're going to have to show at trial. But to say as a matter of law that the defendants' stated reasons were the only reasons, I just can't do it on this record.

Similarly, with the July 27th, 2017, opinion, that was not in response to a question. That was her remarks. But, again, the parties have it, briefly: "Q2 was an outstanding quarter for Celgene I&I highlighted by significant sequential

growth for Otezla. Key Otezla performance indicators continue to strengthen and market share and prescriber adoption increase significantly in both the U.S. and internationally."

Again, talking about gains and treatment adoption: "We have advanced multiple future growth drivers for Otezla" and so forth.

Now, again, the question for me is a genuine dispute of material fact. We know that that turned out not to be an accurate statement based on what happened afterwards, but the question is what was going through Ms. Curran's mind at the time, and that's because they had to revise their guidance in the third quarter.

Again, there have been -- for example, PX-60 there's indication that the underlying data shows that there was a decrease in market share. We've talked about the difference between market growth and market share. They are very different. You can increase your market share in a contracting market, you can decrease your market share in a growth market.

I know that those are two different things. Ultimately, the overall market growth was one of the stated reasons for having to change the guidance from 1.5 to -- approximately 1.8 billion down to 1.25. But I understand the difference between the two.

The key performance indicators, again, that's the

statement she used. Defendants can argue to the jury this is what she meant by key performance indicators.

Plaintiffs can argue this is what key performance indicators are in the industry, but they have presented evidence that based on what at least appears to be sound reasoning that a reasonable investor would consider to be performance indicators that there was information to the contrary, that they were not supporting that statement.

So for that reason I find there's genuine disputes of material facts as to her two statements. Again, scienter and loss causation as to both.

I do not find it appropriate for summary judgment. I'm going to deny the motion for summary judgment as to Ms. Curran.

By the way, before I forget, I did not prepare today because I didn't see it in the briefing as to these arguments as to the SEC filings, 8Q, 10K, 10Qs. That's not the way I read the defendants' motion. I didn't see opposition.

So when I issue this order, I'm going to issue an order based on the motion for summary judgment that the genuine disputes of material fact preclude summary judgment. I'm going to say there's not genuine disputes of material fact that don't preclude summary judgment as to these statements.

If plaintiffs believe they're still part of their case that's alive based on these other filings, I will note that my

summary judgment motion is limited to those. It seems to me that the defense' position is those are not issues. Plaintiffs believe they are issues.

I'd have to go back through the pleadings and see how the case was litigated to make that determination, but it's not the issue that was before me in deciding this.

Turning to ozanimod, ozanimod was developed by Receptos, Inc. In August of 2015 Celgene acquired Receptos. Martin was the managing director of Celgene Receptos from 2016 to March 2018. Until April 2016 he reported directly to Smith.

Smith was the president of Celgene I&I and the chairman of IIEC from 2010 to April of 2017. He then in April of 2017 became the president and COO of Celgene and was no longer a member of the IIEC.

Turning first to the April 27th, 2017, Q1 earnings call, I agree with the defense that there's no genuine dispute of material fact that at that time -- and I wanted to pull up a specific exhibit because it was referenced a lot in the papers -- it was not argued here today -- that Celgene had even confirmed the existence of the metabolite to be sure.

They realized on the testing that there could be a metabolite and they were organizing as to "What do we do if there is a metabolite?" but there was no definitive determination that there was in fact a metabolite.

I just haven't seen any cases that when you have a concern that something may come to fruition but you haven't verified it that that is now material non-public information. That I agree with Ms. Yadava.

If you had to go out and say, "We identified something, we don't know what it is but it could be bad," it would make the disclosure obligations extremely difficult and it would send the company's stock potentially into a tailspin over an issue that really doesn't exist if it turns out it's not, in this case, a metabolite.

Let me just get the exhibit that was given to me.

(Brief pause.)

THE COURT: One of the arguments that was made extensively in the briefing by plaintiffs that when I went back and looked at the actually document -- let me just give you an example.

Plaintiffs' Exhibit 108, that's March 30th of 2017. It's a long e-mail to a number of members. It talks about, "Sorry for the delay, but attached you will find the NDA submission tracking dashboard."

Even there, as of March 27th, all internally it indicates is there's a potential to identify a new metabolite. Even at that point internally they're acknowledging there may be a new metabolite but they have to identify it, and it says why. "The preliminary data from plasma samples in the 1909

study is expected by the end of this week to possibly provide a clue about any potentially new metabolite for RPC1063. Actual data will be available in early May."

At that point they were still trying to determine exactly what they had. They knew it was a potential, and that's the same on Plaintiffs' Exhibit 111. It's an e-mail April 24th of 2017, where the status update says, "It appears that this new peak is real." That's what gave them concern they may have a metabolite. "It's unclear whether it is a single peak, but we are assuming that it is a single peak."

Then it talks about what happens if the metabolite is present, if it's not present. So they're still making plans at this point that if it is a metabolite and it is present, this is how they plan on addressing it. But there still was no confirmation that it was in fact a metabolite.

For that reason, I don't find there's a genuine dispute of material fact as to Smith's statements in April of 2017 because it wasn't even clear internally to Celgene Receptos that they did in fact have a metabolite.

The next statement in July that Smith made -- by the way, Smith just tended to say -- he liked the word "very." "Very, very, very, good. On track for filing" and so forth. He did not give a lot of specifics and he used a lot of "verys."

But what I will note is that the only evidence I have

is that e-mail from Martin to Smith right before he gave the statement. It's Plaintiffs' Exhibit 122. I heard the plaintiffs' argument that this could be interpreted differently. It's July 25th of 2017.

Certainly what's disclosed to Smith is that there is a metabolite. It has been confirmed. However, there's no indication to Smith that it's going to affect the NDA process adversely or that it could impact the NDA process adversely. It follows up with -- after that it says, "Preliminary data indicates that our story remains intact and that approvability is not impacted by this new finding. All the activities that could be done to qualify have been conducted or are ongoing and recent feedback from FDA reviewers" -- that's the FDA consultants -- "indicates that our plan data should be acceptable to the agency and allow us to keep the submission on schedule."

That's what Smith had. I know that there's the e-mail about the material information, I know there's a reference that somebody thought Smith had known about it, but I don't have any definitive evidence that Smith in fact knew about this internal concern.

That's what I need to do first before I start interpreting what that e-mail could mean, if I'm looking at it in the light most favorable to the plaintiffs, which I have to do in this case.

I know that defendants have a different interpretation of the e-mail, but it certainly gives a basis to ask the writer as to "Why did you think Smith knew about it?" And then depending upon what that person said, it might be enough to be considered at this stage, at the summary judgment stage.

But I don't have any information that he was in fact informed. Somebody thought he was informed, but there's no information that he was in fact informed.

So for that reason I'm going to grant summary judgment as no genuine dispute of material facts exist as to Smith's July 27th statement.

That leaves us to the October statement. I view that differently. I do want to say that I -- I actually disagree with the law here, but I'm going to follow the law. I have to.

I agree that this is not a case of the corporate scienter doctrine, if the Third Circuit were going to adopt it, that it would even apply in this case. It's not criminal activity.

It's not as though: "We're going to put this drug on the market and it's going to kill a lot of our patients." We don't have potential criminal activity. This is: Will the NDA be accepted by the FDA?

It may be civil liability, but as far as any type of far-ranging criminal activity, it just doesn't exist. My

disagreement with the law is, I think when the head of the company speaks, as Smith did here, what I think the law should be is he has a reasonable duty to do due diligence before he speaks. I don't think there should be this roadblock "If we don't tell Smith, he can't be liable for it."

I strongly disagree with that, but that is essentially the way the law stands. I have to show that the information was in Smith's head when he made the statement.

I don't like -- it personally bothers me that the heads of companies can insulate themselves from getting potentially bad information and then say, "Well, I'm not liable for what I said."

So in my view, the securities law should say if you are going to speak on behalf of the company, then you have a duty of reasonable diligence and inquiry so that then those other statements could be attributed to him because he didn't do his reasonable diligence and inquiry. I would do it under a reckless prong, obviously not knowing because he didn't know about it.

That's not what the law is at this time, but it really bothers me that -- I see these cases over and over again that the primary spokesperson, leader of the company, didn't know or at least I don't have information showing that he knew about these potential problems with the NDA submission.

That being said, I agree with Ms. Yadava that I don't

have anything in the record that Smith was aware of these internal concerns with the NDA submission. I want to put it in that term. I don't view this as every little problem has to be disclosed.

I agree with that as a proposition, but this wasn't a little problem. This was a product that they made public statements about when the NDA was submitted. It was clear it was going to be year-end of 2017. It was very important to Celgene because they were touting it.

So I don't view that as a little problem, but what I do agree with the defendants on is that this is more just disagreement. Disagreement could be, you know, do you put your client on the stand or not? Right? You have a disagreement about that.

This was there were internal voices directly involved with the product saying that this may not go through. It was a real risk that was understood by those working on the project within the company, and not a metaphysical risk, not a philosophical risk, but a real risk.

Ultimately, we know that the risk turned out that they got the RTF. Right? So that's what occurred here.

But I do agree with the plaintiffs that, given Martin's role in the company and his involvement with the project and the people all working around him, that it is a reasonable inference that Martin knew that this submission was at risk.

As plaintiffs correctly point out -- let me get the timeline correct.

(Brief pause.)

THE COURT: The day after the first statement in October when they did the briefing book, Exhibit 149, to the FDA, Celgene was basically asking the FDA to let them submit this information later concerning the metabolite. So not only was it an internal discussion and they knew that the FDA in general required the long-term studies -- I'm just going to use that term, "LTS," because that's what people use. I've seen other terms as well. I'll just use "long-term studies" on the metabolite, generally what they require in an NDA. They knew that they were asking for something different than that from the FDA.

It's in the briefing book. It's explicitly indicated to the FDA: "We're going to be asking" -- in my words -- "an exception to your general rule."

At a minimum, then, once Martin speaks and he talks about the positive top-line data, I do believe the material omission at that point was to say, "By the way, you know, however" -- it had to be couched in legal terms, I understand -- "we are going to ask the FDA to do something that they generally don't -- that their policy -- it would have to be an exception to the general policy. If the FDA doesn't accept our request, there's a risk that the NDA will

be rejected."

I think that's what had to be disclosed to the market, that this was, in my words, an at-risk NDA submission. I know that you can say philosophically every NDA is at risk because you don't know what the FDA is going to do, but there's a difference between knowing going into it that there's a potential problem and then getting feedback from the FDA that you didn't see coming and you have to go back through other steps as well.

So I will permit the Martin statement to go forward. Much to my chagrin, because I don't think the president and COO should be able to get a pass on these types of statements but I don't have evidence that I can point to to say Smith had this information when he made these statements -- should he have had that information? In my view, absolutely, but that's not the standard that I'm applying at this time.

So I'm going to grant the summary judgment motion as to Smith's three statements. I'm going to deny it as to Martin's statements.

Then, similarly, as to scienter, for the reasons I stated earlier, it's an issue of fact. Again, defendants may be correct, maybe this is not something that Martin thought it was that important; plaintiffs may be correct, he had to know this was important based on the discussions and should have been disclosed, that will go to his scienter.

And then similarly there is loss causation. I have addressed those filings earlier. It's and issue of fact, in my view. I can't say as a matter of law that I have to cut the loss causation out earlier.

Plaintiffs have given me enough that they can go to the jury with those other disclosures and argue that these were the corrective disclosures. I'm not saying a jury will accept those, but I think they have given me enough information that if there's a genuine dispute of material fact that I can't say as a matter of law loss causation does not apply to those disclosures.

What I'm going to do -- as I indicated, I will get an order out. The order will be very specific. I'm going to deny as to Curran, I'm going to grant as to Smith, I'm going to deny as to Martin, I'm going to deny the other portions as well.

If plaintiffs believe that there were other documents that they were relying on to show -- other SEC filings, I just don't have that before me. I'm not in a position to rule on those.

This case will be transferred from me tomorrow, and I will let the new judge know that there seemed to be a disagreement among the parties as to what other statements might be actionable in this case and that I did not rule on those.

MS. YADAVA: Your Honor, I'm very sorry to interrupt and keep Your Honor longer, but one question: Our brief has a whole section called AMF cannot establish defendants' liability for the statements not attributed to Smith or Martin, which are all of the corporate statements, and Your Honor just said that there's no corporate scienter. That's -- all of those statements should be dismissed, as well, because there's no basis for liability from those statements without the doctrine of corporate scienter.

THE COURT: So they go forward on Martin and potentially on these Qs and K filings, I haven't had those, but if Martin is liable, I mean, in reality Celgene is going to be indemnifying him. Right?

MS. YADAVA: Your Honor, it's not about indemnification. It's about what statements remain in this case, and plaintiffs today threw up a whole bunch of 10Qs, 10Ks in random statements. What our understandings now is that the class period on ozanimod would basically be from Martin's October statement, because that's his only statement, through the alleged corrective disclosure. But if Your Honor puts back in all of the corporate scienter statements, which Your Honor said this is not an instance in which corporate scienter should apply, it changes the parameters of Your Honor's decision.

THE COURT: That's a good question. I think actually

it's an evidential issue that is probably going to be extensively addressed in a motion in limine if this case goes, but I think you're right that once you get to that stage and then the trial judge is going to have to make a decision as to what plaintiffs can -- at least make a good-faith basis showing Martin knew or Martin did not know.

So that if Martin knew it or they can at least make a threshold showing that they can argue to the jury that Martin knew it, I think that would be admissible because it goes to his state of mind. If they can't make that threshold showing that Martin was aware of certain information, then I anticipate you're going to be granted the leave you seek now, which is they can't use that against Martin.

MS. YADAVA: Your Honor, I think I'm asking something differently. I'm not asking to use things against Martin. I'm just asking for Your Honor to include in his ruling that the corporate scienter statements are not actionable alleged misstatements because there is no corporate scienter, the doctrine doesn't apply.

So statements in the 10Ks and 10Qs and 8Ks earlier in the class period are no longer in this case because we moved on dismissal of the entirety of the ozanimod claims, including false statements not attributed to Smith or Martin. If plaintiffs thought there were statements that remained, they could have articulated those particular statements that they

articulated in argument today.

But, Your Honor, it changes the contours of the case a little bit and your ruling if we don't know whether the corporate scienter statements are in. My understanding is that's an issue of law as to whether the doctrine of --

THE COURT: You're right. It is an issue of law, but my problem with making that ruling is that I haven't ruled on the -- I don't know what their theory -- first of all, I don't know what the statements were. Second of all, I don't know what their theory of liability on any SEC filings are.

I will agree, as far as my rulings today, that corporate scienter does not apply, but I don't think -- I understand you've asked for it, but I have to be honest, I really didn't focus on any of the SEC filings. I just didn't read it as being an issue.

I don't want to hamstring plaintiffs at this point that if they think there's a Q or K statement that's still actionable as to who they think is liable for it. That I'm going to -- I can say I don't find that the doctrine of corporate scienter applies to the statements I'm ruling on. But I don't want to preclude them in case once they get those Qs and Ks, if they exist, that they say, "Well, this is who is responsible for them."

MS. YADAVA: Your Honor, the Qs and Ks are in the complaint, and pages 52 to 57 of our opening brief explain why

they're not actionable. They responded to it, Your Honor, and so did we in reply.

MR. ZIVITZ: Your Honor, if I may.

THE COURT: Yes.

MR. ZIVITZ: Your Honor, the Ks, the Qs, the 8Ks, as I mentioned earlier, they were corporate statements, they are Celgene statements. Our position is that there was scienter on behalf of Celgene in light of Defendant Martin having furnished information, having tolerated the misstatements, and also the ten other high-level managers that -- Maria Palmisano, Jay Backstrom, Terri Curran, all management-level folks who knew about the metabolite and knew about the risk.

What I would suggest, Your Honor, is Your Honor's point about the statements that Smith issued, the statements that Martin issued, your order is going to refer to those. To the extent -- you're right, whether or not it's motion in limine briefing, we can address it then as to the viability or the additional K and Q and corporate website statements that the company accepted. We can deal with that at a later point, but that is our position.

THE COURT: Right. What I read that issue to be -- I'm referring to pages 52, 53, 54 up to 55, the corporate scienter. What I had read that to be was more can Smith be liable if -- under *Janus*, before I even get to corporate scienter.

The question there was did Smith -- did he have the ultimate authority over certain information. I think the parties agree that ultimate authority over the statement would be sufficient.

I do apologize to counsel because I was not reading that in the context of any SEC filings. That wasn't how I read the argument. I think -- I know there's argument for corporate scienter, but I think both sides agree if somebody had ultimate authority over a filing and sign off that that person could be liable under *Janus*. I wasn't reading that argument in the context of any specific SEC filing.

MS. YADAVA: I think Your Honor just said, though, that you found that Smith didn't have scienter so his scienter cannot be imputed as the maker under *Janus*. Right?

THE COURT: Based on those statements, that's correct. But -- all I will say is if Smith signed off on a statement where they can now say he had the ultimate authority and it was material and misleading, that may be a different issue. I thought you said that Smith wasn't the one who filed the SEC filings.

MS. YADAVA: He didn't. That's the whole point, Your Honor. We point out in here these are attributed to other people. All of the SEC filings are attributed to other people, they are signed by other people, and the *Janus* case and others all say that if you have a filing that's attributed

to someone else, those people are the makers of the statement.

MR. ZIVITZ: Your Honor, if I may, these were all company statements. They are Celgene statements. They are not the -- just the signatory's statements. Otherwise companies could get off the hook and just point the finger at an unknowledgeable signatory.

So our position again is these are corporate statements and the scienter of ten-plus folks, including Martin, who Your Honor found at this stage there is a disputed issue of fact for the jury as to his scienter. All of that scienter goes to Celgene under any test, any *Cognizant* test. They furnished information and they tolerated the misrepresentation so all of those company statements, the Qs, the Ks, the 8Ks, and the corporate website slides, because Celgene accepted them, Martin's scienter and the other folks' scienter is imputed to Celgene for purposes of those statements.

MS. YADAVA: Your Honor, there's only two doctrines valid -- there are the only two doctrines addressing this, the only two doctrines addressed by plaintiffs. One is *Janus*.

Under *Janus*, if you have ultimate authority over a statement and you have scienter, your scienter can be imputed, you can be liable for those statements as the maker. We just found that Smith did not have scienter. He cannot be liable for those corporate statements that Mr. Zivitz just described.

The second doctrine is corporate scienter which only

applies, if it applies at all in the Third Circuit, to egregious circumstances when there's blatantly false statements. We don't have that here. Your Honor has already held that.

The two doctrines addressed in the briefing explain why we are entitled to the summary judgment on all of those additional statements. Your Honor's point that some of these are 10Ks and 10Qs and have other signatories only further bolsters this point, which is why summary judgment should be granted on all of this.

We moved in our papers on all statements relating to ozanimod, had detailed briefing on this, and we don't want Your Honor to, respectfully, say that those may still be in the case because under your rulings they should not be.

MR. ZIVITZ: Your Honor, if I may, just one more point on this.

Your Honor, we talked a lot about who knew what and when. The company, by virtue of all the people that worked on ozanimod, knew about the metabolite, knew about the risk no later than July, certainly knew about the risk by October.

If the company is issuing statements in 10Qs, 8Ks, and a 10K in January, those statements are actionable on behalf of the company by virtue of the folks who had scienter, which is Martin, Curran, Backstrom, Lamb, and others. Just because Smith is out doesn't mean that the scienter of the other

individuals isn't imputed to the company.

Ms. Yadava is not saying it but every case that she relies on is a pleading case. We're talking about evidence. Even under those cases, all three standards: the broad standard, the narrow standard, and the middle approach, which the middle approach and the broad standard is what the *Cognizant* court accepted at the pleading stage -- under those standards, if you furnish misinformation and you tolerate the misstatement, that scienter is imputed to the company.

That's exactly what we have here. To let Celgene get off the hook, that would turn corporate scienter on its head.

THE COURT: Let me just ask Ms. Yadava. I was focused on the individual statements, but what Mr. Zivitz is saying was in accord with my understanding of the law. If a company makes a filing, regardless of who signs it on behalf of the company, the company could be on the hook for it, if nothing else an adopted admission.

But I'm just trying to see what cases you have that say if the company makes a materially false statement or omission in an SEC filing they're not liable for it, only the person who signed off on it could be liable for it.

MS. YADAVA: Sure. Well, Your Honor, the only time there can be liability for corporate statements is if the signatory or the company as a whole had scienter. If you're deciding the company as a whole had scienter, that's the

corporate scienter doctrine that the Third Circuit has not adopted and that is supposed to be used in very rare context.

Mr. Zivitz is trying to explain this idea where we just take people's scienter and we put them all on the corporation. That is the doctrine of corporate scienter which the facts and circumstances do not present here such that corporate scienter should apply.

Your Honor has said this already on the record that corporate scienter does not apply in these instances. There's no blatantly false statements and there's no extraordinary circumstances or egregious culpable conduct, which is why there's no corporate scienter. There is no other theory other than the concept of *Janus*, which plaintiffs argue is basically taking Smith's scienter and imposing it on the company and making him the maker of those statements, but we just determined that Smith doesn't have scienter, so there's no scienter of Smith to impute on the company and he didn't have ultimate authority so he couldn't have anyway.

Even putting aside the ultimate authority point, that point only works if Smith had scienter to impute to the company.

THE COURT: The reason I said the corporate scienter doctrine doesn't apply, besides the fact the Third Circuit hasn't expressly adopted it, is because you need egregious behavior.

MS. YADAVA: Yeah.

THE COURT: To me, under plaintiffs' best case this wasn't that type of behavior. This was disclosing a potential risk that was known to Martin or at least potentially known to Martin -- that's going to be for a jury to decide -- and others that Martin interacted with. That will come down to what Martin knew, when he knew it, and then what his reaction was and whether the jury finds him credible or not.

As to the Qs and Ks, I have not -- I just haven't focused on that issue. I don't want to make a ruling now without having gone through to say who could be liable and Qs and Ks and so forth. My understanding was, if the company makes a materially false statement or omission and there's scienter and there's loss causation and so forth, there could be potential liability for the company.

But I think what you're saying, Ms. Yadava, is if somebody drafts it and they have bad scienter but they don't have the ultimate authority and then somebody else who has the ultimate authority signs off on it not knowing that this is intentionally false or a misstatement, that there's no liability in that case.

MR. ZIVITZ: Your Honor if I may, can I just add one thing?

THE COURT: Sure.

MR. ZIVITZ: The cases that Ms. Yadava keeps bringing

up in terms of saying it has to be egregious, those again are pleading-stage cases. What the court held there in *Cognizant* is we look at egregious situations in order to draw the inference that the company is responsible because we don't have the individuals -- we don't have evidence of the individuals at issue.

Here we have that evidence. We have hard evidence that upper management knew about the metabolite and knew about the risk. That's why I keep saying those pleading cases are inapposite. But, again, even if they apply here -- let's just say that *Cognizant* applies. Under all of those standards what the court held, what Judge Walls held, what Judge Salas held, is if a bad actor, someone with scienter, furnishes information to the corporate entity, which is exactly what Martin and the NDA folks did, or tolerates the misrepresentation after it's uttered, that scienter gets imputed to the company under the pleading standard.

Here, again, we are at the evidentiary standard and we have scores of evidence showing that Martin, Jay Backstrom, Palmisano, Gondi Kumar, the entire company knew about the NDA. The idea that somehow because it's not akin to criminal conduct that somehow the company gets off the hook for being responsible for its statements, that is not at all what the securities law are meant to guard against. Here you have the folks who give the information --

THE COURT: I'm going to reserve on this particular issue, but when I issue the order, I'm going to do an addendum opinion as to this particular issue. Okay.

MR. ZIVITZ: Thank you, Your Honor.

THE COURT: I think it's only fair. I understood the argument differently from defendants. I'm not saying that -- and what Ms. Yadava is saying right now makes sense. That is not the way I read the motion papers.

Let me reserve on the issue, and I'll just do a short addendum as to this particular issue under both *Janus* and corporate scienter and who it could be attributable to. Okay.

MR. ZIVITZ: Thank you, Your Honor.

THE COURT: I think that's the only fair thing at this point. I have to take a look at the issue.

MS. YADAVA: Understood, Your Honor. Thank you.

MR. ZIVITZ: We appreciate it.

THE COURT: Thank you, counsel.

Mr. Cecchi, go ahead.

MR. CECCHI: Judge, I think I would be committing an omission if I didn't say, since this will be the last time we appear before Your Honor, that we certainly appreciate the hard work you did not on this case but in the many years you have been on the bench.

The Bar is going to miss you, I know your colleagues are going to miss you, but we all wish you the best in the

exciting new ventures for you and your family and we will see you again.

THE COURT: Thank you, Mr. Cecchi.

Mr. Cecchi is being remiss because I'm going to work with him on Monday. No, I'm only kidding. I'm not going to work with Mr. Cecchi on Monday or Mr. Lustberg.

MR. LUSTBERG: Actually, coincidentally I'm going to a meeting at what will be your new firm in a few minutes.

THE COURT: Tell them I said "hello."

MR. LUSTBERG: Good luck, John.

THE COURT: Thank you, all.

(Which were all the proceedings held in the above-entitled matter on said date.)

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FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE

I, **Lisa A. Larsen, RPR, RMR, CRR, FCRR**, Official Court Reporter of the United States District Court for the District of New Jersey, do hereby certify that the foregoing proceedings are a true and accurate transcript from the record of proceedings in the above-entitled matter.

/S/Lisa A. Larsen, RPR, RMR, CRR, FCRR

Official U.S. District Court Reporter ~

District of New Jersey

DATED this September 11, 2023

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